IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

In re application of: Michael Wandell et al.	Examiner: Lore Ramillano
Application No.: 10/706,321	Group Art Unit: 1797
Publication No.: 2005/0130310	Publication Date: June 16, 2005
Filed: November 12, 2003	Atty. Docket No.: 36664.00.0013
Title: **QUANTITATIVE ANALYSIS OF A BIOLOGICAL SAMPLE OF UNKNOWN QUANTITY**	

Mail Stop Appeal Brief—Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

APPEAL BRIEF PURSUANT TO 37 C.F.R. § 41.37

Dear Sir:

Appellants submit this brief further to the Notice of Appeal dated September 23, 2008, in the above-identified application.

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I. REAL PARTY IN INTEREST

Home Access Health Corporation is the assignee of all rights and interests in U.S. Patent Application No. 10/706,321 recorded before the USPTO on April 7, 2008, at Reel/Frame 020766/0530, and is the real party in interest in this Appeal. Appeal by an Applicant is proper under 37 C.F.R. § 41.31(a)(1).

II. RELATED APPEALS AND INTERFERENCES

To Appellant's knowledge, there are no related appeals or interferences filed, pending, or decided.

III. STATUS OF CLAIMS

Claims 4–15, 20–21, and 42 are pending.

Claims 4–15, 20–21, and 42 were twice rejected on December 12, 2007, and June 23, 2008, respectively, which are on final rejection and are thus appealed to this Board.

A copy of appealed claims 4–15, 20–21, and 42 as currently presented is attached in Appendix A.

Dependency: Claims 4, 6, and 42 are independent. Claim 5 is dependant upon claim 4, claim 7 is dependant upon claim 6, and claims 7–15 and 20–21 are dependant upon claim 42.

The originally filed application included 41 claims. Claim 42 was added during subsequent prosecution. Claims 22–41 were withdrawn from consideration as being drawn to a nonelected invention. Claims 1–3 and 16–19 were cancelled by Applicant. All appealed claims are currently twice rejected by a nonfinal Office Action. Twice-rejected claims may be appealed even if not in final rejection. 37 C.F.R. § 41.31(A)(1). No claims have been allowed or confirmed.

IV. STATUS OF AMENDMENTS

Dependant claims 5, 7, and 21 are original.

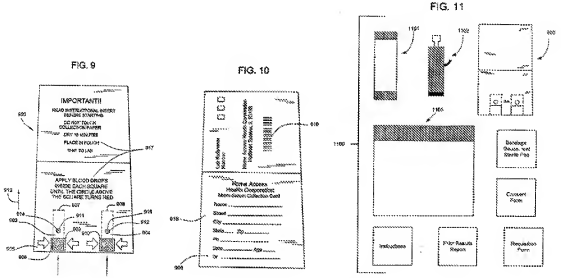
All claims, aside from claim 42, were first rejected on December 12, 2007, by the Examiner. On March 21, 2008, Applicant added claim 42 directed to a kit incorporating all features of claim 4. Dependant claims 8–15 and 20 were amended on March 21, 2008, only to the extent that they were made to depend upon newly added claim 42. The body of these claims has remained unchanged since they were filed in the original application. Claims 4 and 6 were amended to include the subject matter of claim 1 and were rewritten in independent format. No substantive amendments were made to these claims. A final rejection of all claims was issued on June 23, 2008.

A telephone conference was held on August 8, 2008. Applicant filed an after-final response on August 25, 2008, without amendments to the claims. The Examiner maintained her final rejection on September 11, 2008, in an Advisory Action. Applicant filed a Pre-Appeal Brief on September 23, 2008. A Notice of Rejection from the Pre-Appeal Panel was received on December 10, 2008.

V. SUMMARY OF CLAIMED SUBJECT MATTER

References herein are made to the page and paragraph numbers of the specification as filed and published on June 16, 2005, as U.S. Patent Publication No. 2005/0130310A1, a copy of which is attached as Exhibit A.

Medical patients and their doctors do not always have access to medical institutions, but all patients and doctors have access to the postal service. Sending liquid blood specimens through the mail is impractical. The collection by patients of large or fixed quantities of liquid in a vial to be mailed is problematic. One solution is to prick a finger using a pricking device, place the finger over an absorbing tissue, and collect blood that dries on the absorbing tissue for optimal postal delivery. (See paras. 3 and 4.) Claims 4 and 6 and their dependent claims are directed to a fluid collection device 900 shown in FIGS. 9–10 (front and back). Claim 42 and its dependant claims are directed to a kit 1100 shown in FIG. 11 where the fluid collection device 900 is shown as part of the kit 1100.



Figures 9–11 of U.S. Patent Application No. 10/706,321

Remote testing of blood allows patients to preserve some degree of anonymity. During the spread of HIV in the late 80s, the need for remote testing became especially important. (See

para. 4.) There is also a need for remote testing of blood for different medical conditions, such as high cholesterol, lipid profiles, triglycerydes. (See para. 6.) Remote testing can be done by pricking a finger and placing a few drops of blood on an absorbent material, which becomes a dried blood specimen. (See para. 9.) The device includes a fluid collector 903, 904 as shown in FIG. 9 (See para. 44.) This fluid collector is shown in FIG. 9 as a long, rectangular strip and is disposed between a superstrate sheet 905 shown in FIG. 9 and a substrate sheet 906 shown in FIG. 10. (See para. 44.)

The fluid collector shown by the dashed lines in FIG. 9 is an absorbent substrate (see para. 50) coated with saccharide, made of a mat of glass fibers, and at least substantially coated with polyvinyl alcohol. (See paragraph 51.) The fibers have a size that substantially prevents lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking. (See para. 51.) A user places his finger on an aperture 909, 910, said aperture being made in the superstrate sheet 905, and brings the blood drop at the end of the finger in contact with the fluid collector through the aperture. The blood is absorbed in the absorbent substrate between the arrows as shown in FIG. 9. The blood migrates up along arrow 913 until the fluid collector visible via the secondary aperture 911, 912 becomes red with red blood cells. (See para. 44.)

VI. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Only one group is on appeal. Claims 4–15, 20–21, and 42 stand rejected under 35 U.S.C. § 103(a) as being unpatentable over Quattrocchi (U.S. Patent No. 6,014,438) in view of Fitzgerald et al. (U.S. Patent No. 6,528,321).

All independent claims of the group on appeal are directed to a kit or a fluid collection device where the phrases "said superstrate having an aperture defining a blood receiving opening" (claims 4 and 42) and "said superstrate having a pair of apertures, each defining a blood receiving opening" (claim 6) are at issue. The term to be reviewed on appeal is "aperture" within the context of Applicant's claims.

The Examiner explains that "Quattrocchi further discloses a fluid collection device comprising a pair of fluid collectors, and a single superstrate, said fluid collectors ordinarily not being in fluidic contact with one another and each being generally fixed with respect to said superstrate, said superstrate having a pair of apertures, each defining a blood receiving opening and permitting access to a respective one of said fluid collectors." (See June 23, 2008, Final Office Action, p. 3.)

In response to Applicant's request for clarification, the Examiner explained, "In response to applicant's response that Quattrocchi does not have an opening to provide access to a fluid collector, examiner disagrees. During examination, the claims may be interpreted as broadly as their terms reasonably allow. Here, it appears that Quattrocchi's specimen selections (58) may be interpreted to be 'apertures,' because Quattrocchi discloses having an absorbent sample sheet (56), which has small openings to allow the fluid to flow through the sheet. Quattrocchi further discloses in col. 10, lines 33–43, that such specimen sections may be interpreted as apertures

because he discloses having the blood sample 'fill the specimen section on the card.'" (See June 23, 2008, Final Office Action, p. 7.)

VII. ARGUMENT

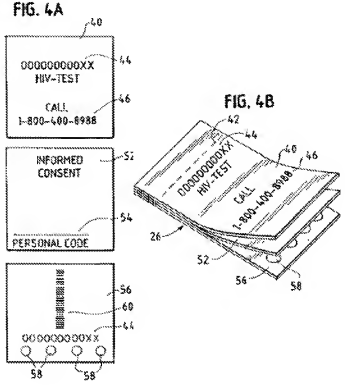
During patent examination, pending claims must be given their broadest reasonable interpretation consistent with the specification. *Phillips v. AWH Corp.*, 415 F.3d 1303 (Fed. Cir. 2005). Words of a claim must be given their plain meeting unless this meaning is inconsistent with the specification. *In re Zletz*, 893 F.2d 319 (Fed. Cir. 1989). Applicant's claims are directed to a superstrate having one or two apertures defining a blood receiving opening and permitting access to said fluid collector.

The term "aperture" can only be found in the claims of the application and at para. [0044] of the specification. The specification provides "at least one aperture (two shown as 909, 910) by which a user may fluidically transfer blood to the collector … To use the device, a user dispenses blood onto the collector, whereby some or all of the blood wicks in the direction shown by arrow 913 until the portions 914, 915 of the collectors 903, 904 visible through the secondary apertures 914, 915 become tinted, whereupon the user is provided with an indication that sufficient blood has been collected." Apertures are openings made in the superstrate to allow a user to place a pricked finger over the fluid collector and not dirty the superstrate. The specification does not give the term "aperture" any special meaning. The term must then be given its plain meaning.

The *Merriam-Webster's Collegiate Dictionary*, 10th ed. defines "aperture" as an opening or open space: hole. In turn, "opening" is defined as something that is open. (See Exhibit B attached hereto.) The term "aperture" is a simple term and is regularly used by claim draftsmen, including Applicant. In *Mechanics of Patent Claim Drafting*, 2nd. ed., Landis explains, "Do not claim holes positively or make them claim elements. Holes are nothing; you cannot claim nothing. Claim "a [member] having a hole, groove, slot, aperture, etc." Section 23 of *Mechanics*

of Patent Claim Drafting, 2nd. Ed. A copy of the relevant pages from this reference is attached as Exhibit C. Applicant's claims are directed to a superstrate with one or two apertures.

In the *prima facie* case, the Examiner cites U.S. Patent No. 6,014,438 (Quattrocchi). Quattrocchi is a decade-old technology owned and created by Applicant. Figures 4A and 4B of the reference show the old fluid collection device of that reference are shown below.



Applicant directs this Board to elements 58. The circles are not openings (i.e., holes) made in the last sheet of paper on this figure, they are small ink circles drawn to indicate where the finger must be placed. This older technology is simpler and has obvious disadvantages. It consists of three card stacked on top of each other. The user was required to rip the cards along dotted line 42, place the finger on a small circle 58 made of ink in the last page 56, and then mail the page to the laboratory. The blood would hopefully fill in the small ink circle that would be punched out of the card and placed in a device for measure.

Quattrocchi at col. 7, ll. 32–42 explains this process:

FIGS. 4A and 4B schematically illustrate one form of blood specimen collection card 26 which is preferably configured in a diagnostic form having three (3) parts. The first part is a removable top sheet 40. Perforations 42 are preferably provided to enable the person being tested to remove the top sheet 40 from the remainder of the collection card 26. Printed on the top sheet 40 is information that the person being tested needs to retrain after the remainder of the collection card 26 is sent for analysis. Col. 6, ll. 54–63.

The second part of collection card 26 is an informed consent form 52. The informed consent form 52 contains a series of statements that the person being tested must read, understand, and acknowledge before a laboratory can perform any test on the specimen. Col. 7, ll. 23–26.

In its illustrated form, the third part of collection card 26 is a blood specimen sample sheet 56. Sample sheet 56 is at least in part a cotton fiber filter paper preferably like that manufactured by Schleicher and Schuell. Sample sheet 56 has a blood collection area specifically designated thereon. In the illustrated embodiment, four similarly shaped sections 58 are outlined thereon for deposit of a specimen in each section. The sections 58 are outlined using black biological ink so that the ink will not interfere with the specimen and an accurate test result can be obtained.

The old technology requires the entire sheet to be made of expensive blood-retaining media. Black biological ink circles are drawn on a flat piece of paper, and users were required to place the finger in the circle and try to get the blood to diffuse over the entire area of the circle. Applicant believes Board members are familiar with this old technology. The ink is biological because the blood, as it flows from the inside of the circle to the outside of the circle must not be tainted with nonbiological ink.

In this old technology, there is no built-in protection for the blood sample when it is mailed out, and the sample would rub directly against other bodies within an envelope during transportation. Once at the laboratory, a circular punch system was used to remove the surface area inside the ink circles to collect the part of the substrate to dilute for measurement. If part of the circle was still white, the measure would be skewed.

The Examiner's confusion here is clear. Examiner's position is best summarized by the continuation comment to the Advisory Action of September 11, 2008: "the Office takes the position that specimen sections (58) may be broadly interpreted to be openings." Broadly

construed, the specimen sections 58, made of small biological ink circles drawn on a page cannot be construed, even if given their broadest reasonable interpretation to apertures.

Further, Applicant's claims read, "an aperture defining a blood receiving opening and permitting access to said fluid collector." (Claim 42). The small ink circles 58 made of biological ink as shown on FIG. 4B of Quattrocchi cannot be reasonably be analogized the elements found in that claim.

Rules are given to the Examiner if she wants to constitute a valid *prima facie* case where ink circles constitute apertures. She must either prove that Applicant's specification supports this particular meaning—that the plain meaning of these words support this interpretation—or that one of ordinary skill in the art agrees with the Examiner. MPEP § 2111. The position taken by the Examiner is contrary to almost every patent claim recorded with this Office. Apertures and openings in a media are precisely that: an aperture or an opening. Applicant asks this Board under what possible circumstance can writing or printing the number 8 on a piece of paper result in creating two apertures?

The use of the term "aperture" and "opening" is well established under modern patent practice. Apertures and openings are normal terminology used to claim holes. The plain meaning of these words is well known and unambiguous. Quattrocchi is a device with a fluid collector having neither an aperture nor an opening. The Examiner's position is contrary to common sense and patent law. The Examiner cannot argue that Applicant's apertures should be broadly construed to include surface areas within ink circles. Accordingly, Applicant requests reconsideration and withdrawal of the rejection and issuance of a Notice of Allowance for all pending claims.

Finally, this argument would not be complete without attempting to understand why the Examiner misconstrues the reference and believes ink circles drawn on a surface of a card can be analogized to openings or apertures made in the card. The Examiner argues, "Here, it appears that Quattrocchi's specimen selections (58) may be interpreted to be 'apertures,' because Quattrocchi discloses having an absorbent sample sheet (56), which has small openings to **allow the fluid to flow through the sheet.** Quattrocchi further discloses in col. 10, lines 33–43, that such specimen sections may be interpreted as apertures because he discloses having the blood sample 'fill the specimen section on the card.'" (See June 23, 2008, Final Office Action, p. 7.)

The Examiner must be reading "the fluid to flow **through the sheet**" as blood moving from a top surface to a bottom surface of the card (e.g., front to back), and hence the circle must by default be an opening of some type made in the sheet. This interpretation is incompatible with any reasonable interpretation of the reference. The members of this Board are familiar with strip technology. A thin absorbent substrate is placed in contact with a fluid (e.g., urine, blood, etc.) at one location and the fluid diffuses through the sheet to cover the other extremity. In the case of the circle on the sheet of the reference, the blood flows through the sheet until it reaches the ink circle. Otherwise there would be no point in using the biological ink except if the ink is in the path of the flow of the blood as described in the reference. The goal is not to soak with blood the reverse portion of the Quattrocchi card 56 but to allow sufficient time and blood for the blood to migrate (flow through) the circle and reach all of the area inside. Applicant is well versed with the Quattrocchi technology, having invented it and used it commercially for over a decade.

VIII. CONCLUSION

If this Board sides with the Examiner, it must conclude that if a pen is used to draw an ink circle on a piece of paper, an apertures or an opening has been created in the sheet. The terms

apertures and openings are terms of art in patent drafting to claim holes that cannot be claimed statutorily. The use of the expression "flows through" in the cited reference, when read for a filtration or absorbing media, represents lateral flow as clearly explained in detail in the reference's specification. Instructions on how to paint a curtain read, "Place the curtain in contact with the ink, it will flow though the tissue until it reaches mark A." Surely this cannot be analogized with a curtain having an aperture or an opening allowing the ink to flow though the curtain.

Obviousness rejections must not be creative associations by Examiners of references drawn unreasonably. Valid obviousness rejections place before an inventor a combinations of enabling prior art that can be presumed to be known by the inventor from a closely related field and that together form the invention under some motivation and expectation of success. In this case, all of the basic elements associated with a proper § 103(a) rejection are missing. Applicant's own invention cited as a reference does not teach a medium with an opening. For the reasons advanced above, Appellant submits that the Examiner erred in rejecting pending claims 4–15, 20–21, and 42 and respectfully requests reversal of the decision of the Examiner.

Respectfully submitted,

Date: January 12, 2009

By: _____
Angelo J. Bufalino, Reg. No. 29,622

Vedder Price P.C.
222 N. LaSalle St., Suite 2600
Chicago, Illinois 60601
phone: (312) 609-7716
fax: (312) 609-5005

APPENDIX A

CLAIMS ON APPEAL

GROUP I—Claims 4–15, 20–21, and 42

4. A fluid collection device comprising a fluid collector with an absorbent substrate coated with a saccharide, said substrate comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking and a superstrate, said fluid collector being generally fixed with respect to said superstrate, said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector.

5. A fluid collection device according to claim 4, said fluid collector having a first end and a second end, said aperture permitting fluidic access to said first end of said collector, said superstrate having a second aperture relatively proximal said second end of said fluid collector.

6. A fluid collection device comprising a pair of fluid collectors, each comprising an absorbent substrate coated with a saccharide, said substrate comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking and a single superstrate, said fluid collectors ordinarily not being in fluidic contact with one another and each being generally fixed with respect to said superstrate, said superstrate

having a pair of apertures, each defining a blood receiving opening and permitting access to a respective one of said fluid collectors.

7. A fluid collection device according to claim 6, said superstrate comprising a second pair of apertures, each of said fluid collectors having a first end and a second end, said blood receiving openings permitting respectively fluidic access to the first end of one of said fluid collectors, said second pair of apertures each being respectively relatively proximal said second end of one of said fluid collectors thereby defining a pair of gangs.

8. A kit according to claim 42, further comprising instructions for using the fluid collection device.

9. A kit according to claim 8, wherein said instructions are integral with said device.

10. A kit according to claim 8, wherein said instructions are separate from said device.

11. A kit according to claim 42, further comprising a requisition form, said requisition form permitting indication of the type of test to be conducted on the fluid to be collected by the device.

12. A kit according to claim 11, wherein said requisition form lists a plurality of test types.

13. A kit according to claim 42, further comprising a dessicant, said dessicant being present in an amount effective to provide a dessicating protective effect on a blood fluid specimen.

14. A kit according to claim 13, wherein said dessicant comprises silica.

15. A kit according to claim 14, wherein said dessicant is contained in a porous pouch.

20. A kit according to claim 42 further comprising a lancet, instructions for using the kit, a dessicant, said dessicant being present in an amount effective to provide a dessicating protective effect on a blood fluid specimen collected in said device, and a barrier film pouch sized for receiving said fluid collection device and said dessicant.

21. A kit according to claim 20, further comprising a requisition form permitting indication of the type of test to be conducted in the fluid to be collected by the device.

42. A kit comprising: a fluid collection device having a fluid collector with an absorbent substrate coated with a saccharide, said substrate comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking and a superstrate, said fluid collector being generally fixed with respect to said superstrate, said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector.

APPENDIX B

EVIDENCE APPENDIX

[NONE]

APPENDIX C

RELATED PROCEEDINGS

[NONE]

US 20050130310A1

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Wandell et al. (43) Pub. Date: Jun. 16, 2005

(54) QUANTITATIVE ANALYSIS OF A BIOLOGICAL SAMPLE OF UNKNOWN QUANTITY

(75) Inventors: Michael Wandell, Mercer Island, WA (US); Ilia Vinogradov, Elmhurst, IL (US); Barbara Godsey, Long Grove, IL (US)

Correspondence Address:
BANNER & WITCOFF, LTD.
TEN SOUTH WACKER DRIVE
SUITE 3000
CHICAGO, IL 60606 (US)

(73) Assignee: Home Access Health Corporation, Hoffman Estates, IL

(21) Appl. No.: 10/706,321

(22) Filed: Nov. 12, 2003

Related U.S. Application Data

(63) Continuation-in-part of application No. 10/421,086, filed on Apr. 23, 2003.

(60) Provisional application No. 60/374,629, filed on Apr. 23, 2002.

Publication Classification

(51) Int. Cl.[7] G01N 33/92

(52) U.S. Cl. 436/71

(57) ABSTRACT

Disclosed is a method for testing a modified specimen such as a dried blood spot, plasma or serum specimen, for an analyte of interest, such as cholesterol. In accordance with the disclosed subject matter, the level of the analyte of interest in the medium from which the modified specimen was obtained (e.g., from a patient's blood) is determined based on the level of an analyte in a solution formed from the modified specimen and on the level of at least one normalizing analyte. The analyte and normalizing analyte each may be an ion, compound, biochemical entity, or property of the specimen. Also disclosed are a fluid collector and a fluid collection device.

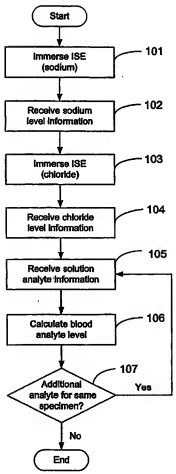


FIG. 1

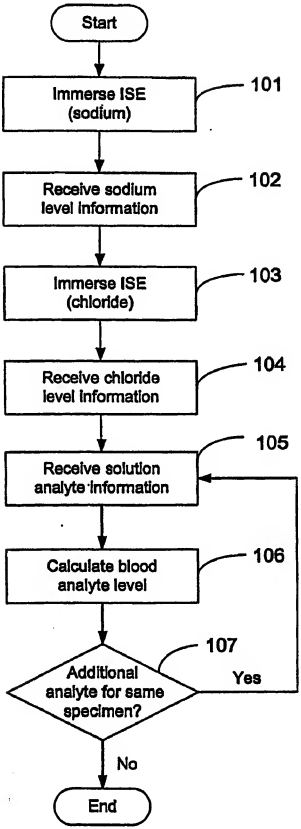

Start
Immerse ISE (sodium)
101
Receive sodium level information
102
Immerse ISE (chloride)
103
Receive chloride level information
104
Receive solution analyte information
105
Calculate blood analyte level
106
Additional analyte for same specimen?
107
Yes
No
End

FIG. 2

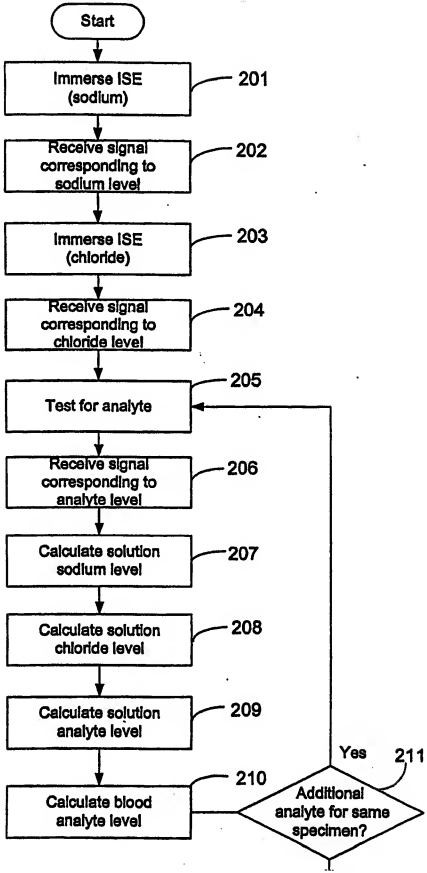

Start
Immerse ISE (sodium)
201
Receive signal corresponding to sodium level
202
Immerse ISE (chloride)
203
Receive signal corresponding to chloride level
204
Test for analyte
205
Receive signal corresponding to analyte level
206
Calculate solution sodium level
207
Calculate solution chloride level
208
Calculate solution analyte level
209
Calculate blood analyte level
210
Additional analyte for same specimen?
Yes
211

FIG. 3

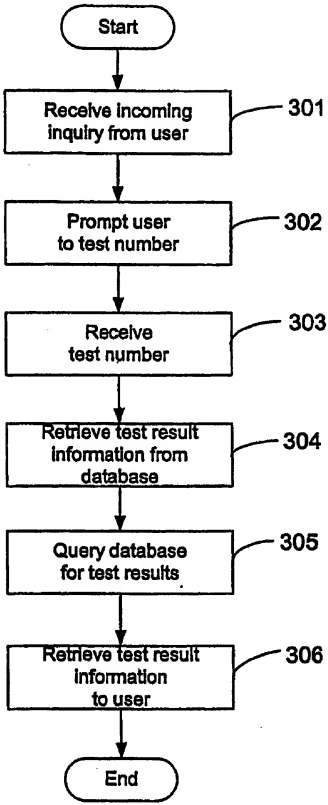

Start
Receive incoming inquiry from user
301
Prompt user to test number
302
Receive test number
303
Retrieve test result information from database
304
Query database for test results
305
Retrieve test result information to user
306
End

FIG. 4

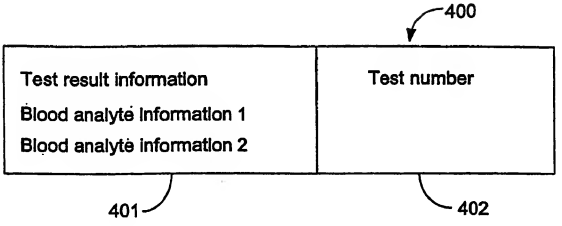

400
Test result information
Blood analyte information 1
Blood analyte information 2
Test number
401
402

FIG. 5

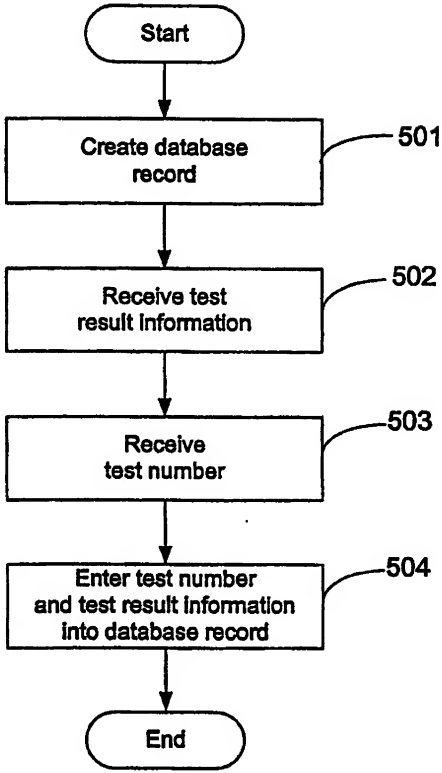

Start
Create database record
501
Receive test result information
502
Receive test number
503
Enter test number and test result information into database record
504
End

FIG. 6

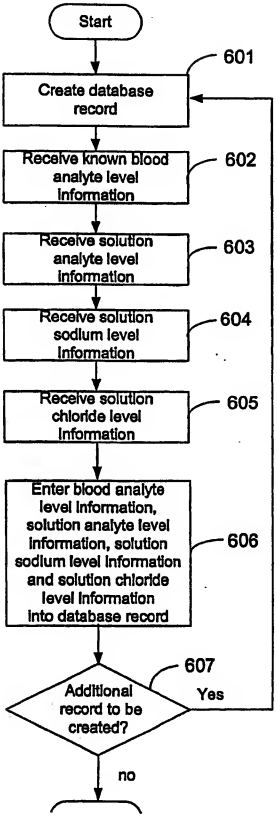

Start
601
Create database record
602
Receive known blood analyte level information
603
Receive solution analyte level information
604
Receive solution sodium level information
605
Receive solution chloride level information
606
Enter blood analyte level information, solution analyte level information, solution sodium level information and solution chloride level information into database record
607
Additional record to be created?
Yes
no

FIG. 7

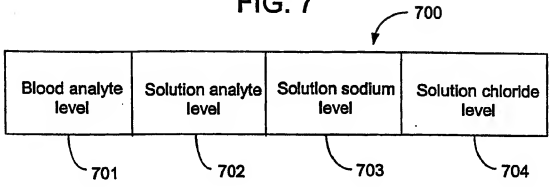

700
Blood analyte level
Solution analyte level
Solution sodium level
Solution chloride level
701
702
703
704

FIG. 8

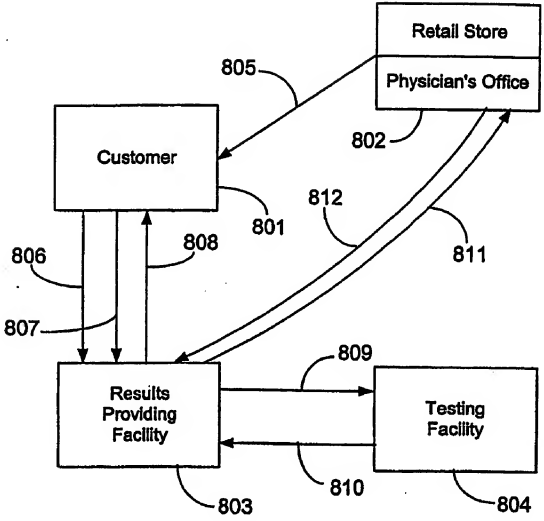

Retail Store
Physician's Office
805
802
Customer
801
812
811
806
808
807
809
Results Providing Facility
Testing Facility
810
803
804

FIG. 9

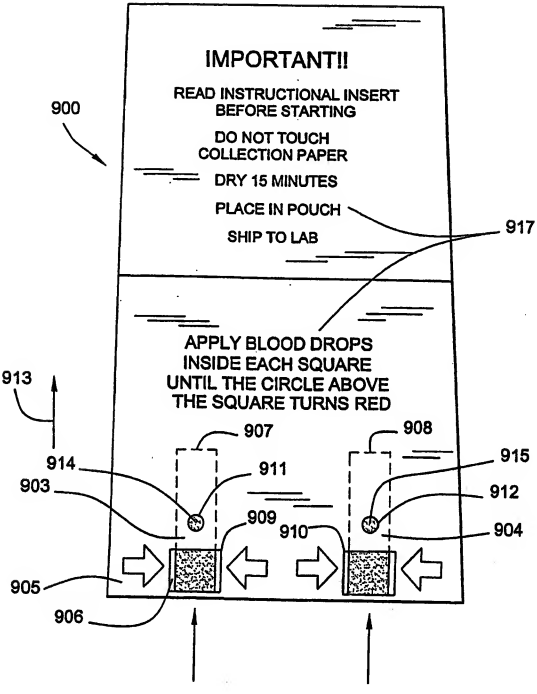

IMPORTANT!!
READ INSTRUCTIONAL INSERT BEFORE STARTING
DO NOT TOUCH COLLECTION PAPER
DRY 15 MINUTES
PLACE IN POUCH
SHIP TO LAB
APPLY BLOOD DROPS INSIDE EACH SQUARE UNTIL THE CIRCLE ABOVE THE SQUARE TURNS RED
900
913
914
903
905
906
907
908
911
909
910
915
912
904
917

FIG. 10

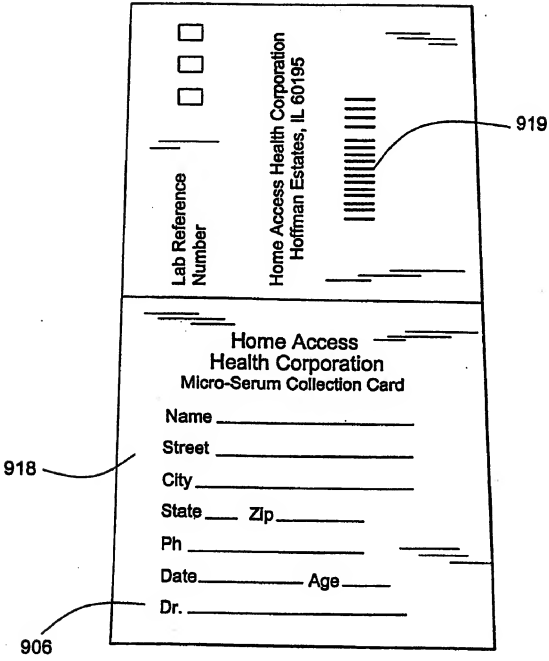
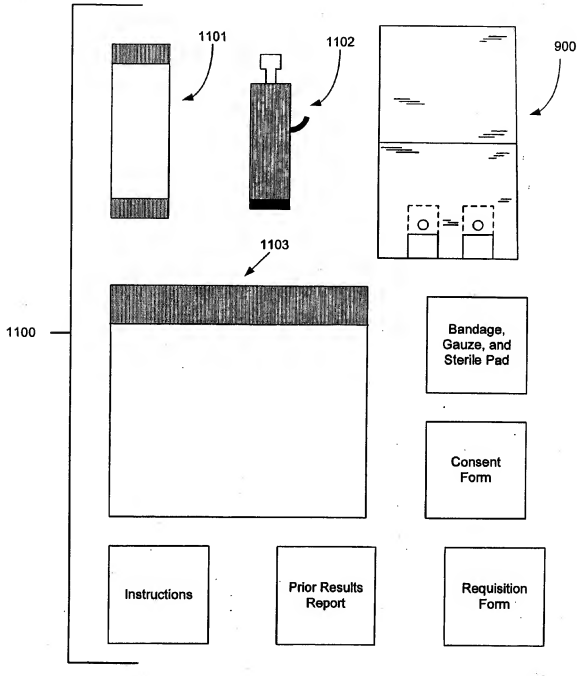

Lab Reference Number
Home Access Health Corporation
Hoffman Estates, IL 60195
919
Home Access
Health Corporation
Micro-Serum Collection Card
Name
Street
City
State Zip
Ph
Date Age
Dr.
918
906

FIG. 11


1101
1102
900
1103
1100
Bandage, Gauze, and Sterile Pad
Consent Form
Instructions
Prior Results Report
Requisition Form

QUANTITATIVE ANALYSIS OF A BIOLOGICAL SAMPLE OF UNKNOWN QUANTITY

RELATED APPLICATION

[0001] This application is a continuation-in-part of U.S. patent application Ser. No. 10/421,086, filed Apr. 23, 2003, which claims priority to prior application Ser. No. 60/374,629 filed Apr. 23, 2002. Both prior applications are hereby incorporated by reference in their entireties.

TECHNICAL FIELD OF THE INVENTION

[0002] The invention is in the field of testing, in particular quantitative testing, and in preferred embodiments medical testing. In highly preferred embodiments, the invention is directed towards the testing of body fluid specimens, in particular blood or serum specimens.

BACKGROUND OF THE INVENTION

[0003] Modern medical and wellness practices increasingly make use of self-administered tests and self-collection of test specimens. For instance, U.S. Pat. Nos. 5,978,466; 6,014,438; 6,016,345; and 6,226,378, issued to Richard Quattrocchi and assigned to Home Access Health Corporation of Hoffman Estates, Illinois, all disclose a method of anonymously testing for a human malady. In accordance with certain embodiments of the subject matter disclosed in the foregoing patents, a patient obtains a blood specimen, typically by pricking his or her finger, and allows the blood to wick onto a blood spot card. After the card has dried, the user then sends the blood spot card to a medical testing facility, where it is tested to determine whether the patient is afflicted with a specific malady. The user may contact the facility anonymously to receive the test result.

[0004] The subject matter of the foregoing patents is usable in connection with testing for the presence of human antibodies directed against viral antigens in the blood, for instance, in determining whether a patient is infected with HIV (human immuno-deficiency virus) or with a hepatitis virus. Another document, U.S. Pat. No. 5,435,970, issued to Mamenta et al. and assigned to Environmental Diagnostics, Inc. of Burlington, N.C., discloses a device for separating blood cells from biological fluids, for instance, for separating serum from whole blood. The device disclosed in the '970 patent purports to enable the shipment and testing of a serum sample.

[0005] The blood spot and serum specimen cards known in the art are suitable for use in the collection of specimens for qualitative testing, i.e., testing for the presence or absence of a given compound in blood or a given medical condition. Heretofore, however, such blood spot and serum cards have been somewhat unsatisfactory in the quantitative testing of blood and serum specimens.

[0006] For instance, general wellness protocol indicates the measurements of a patient's total cholesterol value, which is the number of milligrams of total cholesterol in a deciliter of blood. The value is often used in conjunction with a full lipid profile, which provides levels of triglycerides, HDL (high density lipoprotein) cholesterol, and LDL (low density lipoprotein) cholesterol in a patient's blood. It can be very difficult to gauge the amount of blood or serum that is present in the blood or serum spot card. Particularly when the blood or serum spot card has been self-prepared by a person without medical training, it is difficult to know to certainty whether the spot card has been "underfilled" with less than the intended quantity of blood or serum or "overfilled" with more than the intended quantity. If the amount of blood and serum varies by even a small amount over or under the expected level, the usefulness of the quantitative test can be severely diminished. For instance, it is generally thought that a person's total cholesterol number should be under 200 mg/dl, with cholesterol numbers above 240 mg/dl being considered high and with intermediate cholesterol number being deemed borderline. A 10% margin of error in a cholesterol determination of 220 mg/dl provides no information as to whether the person's cholesterol level is low, intermediate, or high.

[0007] In recognition of these problems, the prior art has provided attempts to provide a quantitative determination of analyte levels in a blood specimen. For instance, U.S. Pat No. 6,040,135, issued to Steven Tyrell and assigned to Biosafe Laboratories, Inc., Chicago, Ill., purports to disclose a method for correcting for blood volume in a serum analyte determination. The method that is purportedly disclosed by this document is limited and is believed generally to be somewhat unsatisfactory.

[0008] The invention seeks to improve upon prior art testing methods, and to provide a method for quantitative testing of modified specimens such as dried blood spot and dried serum specimens.

THE INVENTION

[0009] The invention provides multiple embodiments in the field of testing, in particular medical testing. In accordance with the invention, a modified specimen, preferably a dried blood fluid sample, such as a dried serum or dried whole blood specimen of unknown quantity, is eluted (re-solubilized) and then tested for an analyte. The level of analyte in the blood from which the modified blood specimen was obtained is determined from the level of analyte in a solution formed from the blood specimen. A normalizing analyte, which in the preferred embodiment is sodium ion, chloride ion, and/or osmolality, is measured and is used in conjunction with the solution level of analyte to determine the level of analyte in the blood from which the modified specimen was obtained. The invention is not limited to the field of medical testing but, to the contrary, is useful in connection with other forms of testing. The invention further provides methods for preparing a database of test results, for preparing a regression using a database of test results, and for providing test results to a user.

[0010] In alternative embodiments the invention further encompasses a fluid collector that includes an absorbent substrate coated with a saccharide. A device that includes the collector (as described hereinbelow) also is encompassed by these embodiments.

[0011] Other features of preferred embodiments of the invention are set forth hereinbelow.

BRIEF DESCRIPTION OF THE FIGURES

[0012] **FIG. 1** is a flowchart representing steps in a method for calculating the level of an analyte in blood from which a blood specimen was obtained.

[0013] **FIG. 2** is a flowchart representing steps in an alternative method for calculating the level of an analyte in blood from which a blood specimen was obtained.

[0014] **FIG. 3** is a flowchart representing steps in a method for providing test result information to a user.

[0015] **FIG. 4** is a representation of a database record correlating test result information with a test number.

[0016] **FIG. 5** is a flowchart representing steps in a method for preparing a database of test results and test numbers.

[0017] **FIG. 6** is a flowchart representing steps in a method for preparing a database of blood analyte levels, solution analyte levels, and solution normalizing analyte levels.

[0018] **FIG. 7** is a representation of a database record for a database containing blood analyte level information, solution analyte level information and solution normalizing analyte level information.

[0019] **FIG. 8** is a schematic illustration showing various communications between a customer, a results providing facility, and others in connection with a testing protocol.

[0020] **FIG. 9** is a perspective view of the obverse side of a blood collection device useful in conjunction with the invention.

[0021] **FIG. 10** is a perspective view of the reverse side of the device shown in **FIG. 9**.

[0022] **FIG. 11** is a representation of a kit useful in conjunction with the invention.

DESCRIPTION OF THE PREFERRED EMBODIMENTS

[0023] The invention is applicable to the testing of any specimen that is modified from its original form prior to testing. Most commonly, the specimen is a dried specimen, which has been dried to facilitate storage or transport of the specimen or for other purposes. In preferred embodiments of the invention, the specimen is a medical specimen, and in highly preferred embodiments of the invention, the specimen is a blood fluid specimen, by which is contemplated a dried blood spot, a dried serum spot (for instance, as obtained from the device disclosed in U.S. Pat. No. 5,435,970 or that shown in U.S. Pat. No. 4,839,296 issued to Kennedy, et al. and assigned to Chem-Elec, Inc. of North Webster, Ind.), or another blood fluid specimen. The invention is applicable to the testing of the modified specimen for any suitable purpose, and in particular to testing for any analyte in the specimen. For instance, when the specimen is a blood fluid specimen, the test may be a test for prostate specific antigen (PSA), alanineamino transferase (ALT), lipids, such as triglycerides, high density lipoprotein (HDL), low density lipoprotein (LDL), or any other analyte of interest. The invention is applicable to the determination of the level of analyte in the original specimen, for instance, the level of total cholesterol in the blood from which a blood fluid specimen has been obtained. The "level" of the analyte can be expressed in any suitable units, such as molar concentration, weight concentration, or the like. Blood serum is particularly preferred, but it is contemplated that other fractions such as cells, platelets, gamma globulins, plasma or the like may be employed. For instance, it may be designed to test blood cells in connection with a fasting plasma glucose test. More generally, any body fluid is susceptible to analysis in conjunction with the invention. In light of the foregoing, the preferred embodiments of the invention will be further described with respect to the determination of the lipid profile in a blood sample, but it should be understood that the invention is not limited thereto.

[0024] The facility or other entity that performs the test of the blood fluid specimen may or may not be the same entity that calculates the level of the analyte in the blood fluid specimen or the entity that receives an inquiry from a user and reports the test results to the user. To test the blood fluid specimen, the specimen is first received by the testing entity and is eluted with a liquid, preferably deionized water. It is contemplated that the liquid may be a non-aqueous liquid or may be an aqueous solution, preferably a solution that is free or essentially free of sodium ions or any other normalizing analyte. Alternatively, the solution may have a known amount of the normalizing analyte that can be taken into account during normalization. Preferably, when the testing entity is a testing facility that is intended to test numerous specimens, the eluant is added in a standard amount, which typically is 600 μl (0.6 ml). The eluant in some embodiments may be a buffered electrolyte solution.

[0025] After eluting the specimen, preferably the specimen first is tested for the content of a normalizing analyte, such as sodium and chloride content, and in some embodiments osmolality, which generally represents total content of sodium, glucose, and blood urea nitrogen (BUN). To test for sodium and chloride, an ion specific electrode (ISE), such as that sold by Orion may be employed. Preferably, information concerning both the sodium and the chloride content of the solution are obtained, the information being, for instance, analog information such as an electrical signal or digital information such as a printout representing the sodium or chloride content or a digital signal containing information concerning the sodium or chloride content. Most preferably, osmolality also is measured. It should be noted that the invention is not limited to the use of sodium or chloride as normalizing analytes, but to the contrary, any other analyte (which includes a property such as osmolality) may be measured. It is contemplated in preferred embodiments that the sodium, chloride, and osmolality levels are measured against a predetermined range to determine whether the amount of serum is sufficient to perform an adequate test. For instance, it is contemplated that for a cholesterol test, there ideally should be at least approximately 15-17 μl of serum available for testing. If the solution content of the eluted solution demonstrates that the serum level is far outside this range, the specimen may be rejected as unsuitable for testing. Generally, the specimen may be rejected if there is insufficient serum in the solution, although it is contemplated that in some cases excess serum may be grounds for rejection. Persons skilled in the art may determine how far outside of the desired range the content of normalizing analyte may be allowed to vary without triggering rejection of the specimen.

[0026] Before or after the levels of the normalizing analytes are determined (but preferably after), the solution can be split into four aliquots, or "channels." Each channel is then respectively tested for triglyceride level, HDL level,

LDL level, and in a preferred embodiment, ALT level (which may be of interest in informing a physician whether the patient has an abnormal liver which would contraindicate the use of certain drugs). The analyte levels are measured using any technique known in the art or otherwise found to be suitable. For instance, a cholesterol test is disclosed in Allain, C. C., Poon, L. S., Chan, G. S. G., Richmond, W., and Fu, P. C., *Clin. Chem.* 20:474-75 (1974); see also Roeschlau, P. Brent, E. and Gruber, W A., *Clin. Chem. Clin. Biochem.* 12:226 (1974). A test for HDL is disclosed in RiFai, N., Warnick, G. R., Ed., *Laboratory Measurement of Lipids, Lipoproteins, and Apolioproteins* (1994). A test for triglycerides is disclosed in McGowan, M. W., Artiss, J. D., Strandbergh, D. R., Zak, B. *Clin. Chem.* 29:583 (1983). A test for the liver enzyme ALT is disclosed in Wroblewski, F., LaDue, J. S., *Proc. Soc. Exp. Biol. Med.* 34:381 (1956). The invention is not limited to the foregoing tests or analytes, but to the contrary is applicable to other tests for these or other analytes.

[0027] After the analyte levels have been measured, the level of at least one analyte (and preferably all analytes) in the blood from which the blood fluid specimen was obtained is calculated or otherwise determined based on the solution level of the analyte and on the solution level of at least one normalizing analyte. It is contemplated that the calculation of a blood analyte level may be as simple as multiplying the solution analyte level by the ratio of the blood normalizing analyte level to the solution normalizing analyte level, the blood normalizing analyte level being estimated based on the mean of a normal population distribution. For instance, it is believed that the normal blood sodium level in humans ranges from 136 to 142 mEq/L with a mean of 139 mEq/L and the normal chloride level ranges from 95 to 103 mEq/L with a mean of 99 mEq/L. It is contemplated that through the use of two normalizing analytes, the blood analyte level may be determined by calculating the blood analyte level based on the first normalizing analyte level, calculating the blood analyte level based on the second normalizing analyte level, and then calculating the mean average of the blood analyte levels thus determined.

[0028] If additional normalizing analytes are evaluated, the mean average of all blood level analytes thus determined may be calculated; if desired, where there are at least two normalizing analytes, the average may be weighted towards a specific normalizing analyte. For instance, it is contemplated that Bayesian statistical methods may be used to assign a relative weight to the blood analyte levels determined with reference to each analyte. Such statistical techniques may take into account not only the absolute magnitude of the level of the normalizing analyte level but also the difference between the actual level and the magnitude expected based on the expected amount of serum, and the standard deviation of the normal population distribution of the analyte. These techniques, sometimes referred to as "maximum likelihood" or "prior probability analysis" techniques, may be used to provide an approximation of the blood analyte level. Further testing concerning such statistical techniques may be found in Casella, G., Berger, R. L., *Statistical Inference* (1990) and Carlin, B. P., Louis, T. A., *Bayes and Empirical Bayes Methods for Data Analysis* (2d Ed. 2000).

[0029] Further details concerning the distribution of sodium, chloride, and osmolality in the normal human population may be found in Ravel, *Clinical Laboratory Medicine* (6th Ed. 1995); see also Penney, M. D. and Walters, G., *Ann. Clin. Biochem.* 24:566-71 (1987) and Fraser, C. G., Cummings, S. T. Wilkinsen, S. O. et al., *Clin Chem.* 35:783-86 (1985). It is further contemplated that a more complicated function of solution analyte level and the levels of one or more normalizing analytes may be employed to calculate the blood analyte levels.

[0030] With reference now to **FIG. 1**, the generalized method shown therein is applicable where the same entity performs the test and calculates the blood analyte level. Thus in steps **101** and **102** respectively the ISE (e.g., sodium) is immersed into the solution, and sodium level information is obtained. The steps are repeated for the receipt of chloride information, as shown in steps **103** and **104**. Information concerning the analyte of interest is received in step **105**, and the blood analyte level is calculated in step **106**. If, in step **107**, it is desired to test an additional analyte for the same specimen, control passes to step **105** where the solution analyte information is received for the new analyte. It is contemplated that the steps of testing for the analytes of interest and the normalizing analytes may be performed by one entity and that the calculation of the blood analyte level may be performed by a separate entity. Thus, for instance, in **FIG. 1**, steps **101** and **103** may be omitted if the entity calculating the blood analyte level is not the same entity as the entity that performs the test. The method outlined in **FIG. 1** is very general, and other steps may be added, steps may be omitted or performed in a different order, and more generally the method may be otherwise performed. For instance, steps of elution and verifying proper serum level are not shown, but are preferably employed.

[0031] It is contemplated that the analyte level, first normalizing analyte level, and second normalizing analyte level may be independently determined and these values used to calculate the blood level of the analyte. For instance, the cholesterol tests hereinbefore discussed typically are performed via enzymatic techniques in which the optical density of a solution is measured. The "cholesterol value" of the solution then may be expressed as:

$$CV_s = f(OD)$$

[0032] wherein CVs, the solution cholesterol concentration, is calculated as a function of the optical density, OD, when analytical reagents are added to the sample in accordance with testing techniques known or otherwise found to be suitable. The solution sodium concentration, or Na_s, may be used to calculate the blood cholesterol level, CV_b, in the following manner:

$$CV_b = f(CV_s, Na_s)$$

[0033] Numerous other forms of such calculations are possible. For instance, a correction factor (CF) may be determined as a function of the solution's sodium level, wherein:

$$CV_b = f(CV_s, CF)$$

and

$$CF = f(Na_s)$$

[0034] It is alternatively contemplated that a single apparatus or system may be designed for the calculation of blood analyte levels, wherein an analog or digital electrical signal is generated corresponding to the levels of analyte and normalizing analyte in the solution. For instance, the blood

cholesterol number may be calculated as a function of the magnitude of two electrical signals:

$$CV_0=f(E_1, E_2)$$

[0035] wherein E_1 represents the magnitude of an electrical signal received from a spectrophotometer in measuring optical density for purposes of evaluating total solution cholesterol level and E_2 represents the magnitude of an electrical signal received from an electrode specific to sodium.

[0036] In actual practice, it is contemplated that numerous variables will affect the results obtained for a given set of specimens. For instance, the readings obtained from an ISE may "wander" from day to day, and the device used to collect the blood or other fluid specimen may contain impurities (such as sodium) that have the potential to introduce errors into the test. For this reason, from time to time a "tare" procedure may be employed. Periodically, a plurality of specimens having a known or measurable analyte level is provided, and from these specimens are prepared modified specimens, the modified specimens being specimens as modified in the manner expected of the unknown specimens. For instance, some number (e.g., six) blood specimens may be periodically placed onto a blood spot collection device similar to those used in the field and dried, followed by elution of the dried samples to form solutions. The solutions are then tested for the level of the analyte and one or more normalizing analytes. From these tests, an algorithm for determining the original fluid analyte level as a function of the measured analyte level and the levels of the normalizing analyte or analytes may be derived. Using this algorithm, modified fluid specimens may be analyzed, wherein the levels of analyte and normalizing analyte may be measured, and the level of analyte in the original specimen may be determined as a function thereof. Errors introduced by impurities (such as sodium) in the collection device will be resolved by this methodology, and errors introduced by factors such as machine calibration will be resolvable with periodic re-calculation of the algorithm. The tare procedure may be performed occasionally or regularly at predetermined intervals (e.g., every day, week, month, or year).

[0037] The foregoing exemplary equations are not meant to be exhaustive but, to the contrary, are intended to illustrate that innumerable variants of the methods for calculating the blood analyte level are included within the scope of the invention. For instance, with respect to **FIG. 2**, in one such variant, an ISE (sodium) is immersed into an eluted sample at step **201**, and a signal corresponding to the sodium level is received at step **201**. The signal may be a digital signal, or may be an analog signal, the level of which is recorded. At steps **203** and **204**, the same steps are repeated for chloride level, and at steps **205** and **206** respectively, a test for the analyte is performed and a signal is received corresponding to the analyte level. At step **207**, the solution sodium level is calculated; at step **208**, the chloride level is calculated, and at step **209**, the solution analyte level is calculated. At step **210**, the blood analyte level is calculated, in this instance based on the magnitude of the solution sodium level, the solution chloride level, and the solution analyte level. If, at step **211**, it is desired to test for an additional analyte for the same specimen, control passes to step **205**. In such case, if the solution sodium and chloride level have been stored, steps **207** and **208** may be omitted after a signal is received corresponding to the second analyte level. The process may be controlled by any suitable microprocessor or microcontroller (not shown).

[0038] As stated hereinabove, it is contemplated that the entity who provides test results to a user, who may or may not be the health care professional who has ordered the test, in turn may be the same or different entity from the entity which performs the calculation of the blood analyte level, which in turn may be the same or different entity from the entity which tests the specimen and generates information corresponding to the analyte level or levels and the normalizing analyte level or levels. A very general protocol for a results providing facility is set forth in **FIG. 3**, wherein an inquiry is received from a user at step **301**, and the user is prompted for his or her test number at step **302**. At step **303**, the test number is received, and at step **304**, a test result database is queried for test result information. The information is received at step **305** and is provided to the user at step **306**.

[0039] With further reference to **FIG. 4**, the test result database described above may be structured in any suitable manner. With respect to, for instance, database record **400**, the test result information **401**, which in the illustrated embodiment includes two items of information, blood analyte information **1** and blood analyte information **2**, is correlated with the test number **402**. The test number may be an anonymous test number or may be a test number that is associated with a user, for instance, elsewhere in the database record **400** (not shown) or in a different database.

[0040] With reference to **FIG. 5**, the database may be prepared by creating a database record (shown in step **501**), receiving test result information and a test number (shown in steps **502** and **503** respectively) and, as shown in step **504**, entering the test number and test result information into the database record. More information concerning the role of a results providing facility in a medical or wellness testing protocol can be found in the aforementioned Quattrocchi patents and in copending application Ser. No. 09/709,884.

[0041] The invention additionally contemplates a method for preparing a database for use in calculating blood analyte levels. The blood analyte level may be calculated with specific reference to the database, or alternatively the database may be used in conjunction with the preparation of an algorithm for enabling blood level calculation. The database preferably is prepared with reference to blood having a known level of cholesterol or other analyte of interest. Plural specimens of blood having different levels of the analyte are then reduced to an modified specimen, such as a blood spot or serum specimen, and each specimen is analyzed for the analyte of interest and for a normalizing analyte. For instance, with respect to **FIG. 6**, a database record is created at step **601**, and known blood analyte level information is received at step **602**. Information as to the solution analyte level and the level of two normalizing analytes, sodium and chloride, for example, are received at steps **603**-**605**, and at step **606**, the information received is entered into the database record. If, at step **607**, an additional database record is to be created, control passes to step **601**, wherein a new database record is created for the new specimen. It should be noted that the order of the steps is not critical, and indeed the database may be prepared sequentially with respect to each blood specimen (i.e., each specimen is reduced to an modi-

fied specimen, tested, and the results entered into a database record prior to altering the next specimen of blood), sequentially with respect to database record (wherein all of the blood specimens are reduced to modified specimens prior to entering the first database records) or by any other suitable methodology. A database record **700** as shown in **FIG. 7** is thus prepared, with entries **701** through **704** representing respectively blood analyte level, solution analyte, solution sodium level, and solution chloride level.

[**0042**] As discussed above, rather than being calculated, the blood analyte level in a blood fluid specimen may be determined with reference to the database, for instance, by finding the solution analyte level and solution normalizing analyte level or levels in the database that are closest to those of the specimen. Alternatively, any suitable statistical or mathematical technique may be used to derive an algorithm for calculating the blood analyte level from the solution analyte level and at least one normalizing analyte level. In some embodiments, the algorithm is first order with respect at least to the solution analyte level, and may be first order with respect to the solution analyte level and one or both normalizing analyte levels.

[**0043**] The invention preferably is conducted in accordance with the general schematic set forth in **FIG. 8**. Generally the customer **801** purchases a test kit from a physician or retail store **802** (transfer of the kit is shown via transfer communication **805**) or in other embodiments a patient is provided with a test kit by or at the direction of a health care provider. The test kit (not shown in **FIG. 8**) preferably includes instrumentalities for allowing the customer to obtain a blood, serum or serum spot specimen. For instance, as discussed more fully in the aforementioned Quattrocchi patents, the test kit may include a lancet for pricking the user's finger, a blood spot card, or serum spot card, (or the device shown in **FIGS. 9 and 10** hereinafter discussed) an informed consent form, and a test number. After preparing the blood, serum or serum spot card, the customer sends the dried blood specimen to a results providing facility **803** as shown via transfer communication **806**. In the illustrated embodiment, the results providing facility **803** sends the specimen to a separate testing facility **804**, as shown via transfer communication **809**. As shown via communication **810**, the testing facility provides the test results to the results providing facility. The results may be "raw" results, i.e., results in which the level of the analyte in the blood has not been determined or obtained, or alternatively the testing facility may calculate the blood analyte level and report that result to the results providing facility. As shown at communication **807**, the customer contacts the results providing facility, and at communication **808**, the results providing facility provides the test results to the customer. Optionally, the results providing facility may be equipped to communicate directly with the physician's office, as shown at communications **811** and **812**. Except where transfer of a physical specimen is required, the communication may be made via any means or method now known or hereinafter discovered, for instance, via telephone, wireless communication, electronic mail or "chat" or other electronic communication, or other form of communication.

[**0044**] With reference now to **FIGS. 9 and 10**, the illustrated fluid collection device **900** includes two gangs **901**, **901**, each comprising a fluid collector **903**, **904** that is disposed between a superstrate sheet **905** and a substrate sheet **906** and that is generally fixed with respect to the superstrate sheet **905**. The fluid collector is ordinarily connected to the substrate sheet **906** (a portion of which is visible) at one end **907**, **908**, although the collector may be flexible and thus not entirely fixed with respect to the substrate sheet **905**. The substrate is provided with at least one aperture (two shown as **909**, **910**) by which a user may fluidically transfer blood to the collector. In the illustrated embodiments, secondary apertures **911**, **912** are provided. To use the device, a user dispenses blood onto the collector, whereby some or all of the blood wicks in the direction shown by arrow **913** until the portions **914**, **915** of the collectors **903**, **904** visible through the secondary apertures **914**, **915** become tinted, whereupon the user is provided with an indication that sufficient blood has been collected. As illustrated, the device preferably is disposed horizontally relative to the ground during the wicking of blood. Any other suitable indicator that an amount of blood predetermined to be adequate may be provided. In the illustrated embodiments, instructions **917** are provided on the substrate sheet **905** and identification information spaces **918** (shown in **FIG. 10**) are provided on the substrate sheet **906**. The device may be provided with non-textual machine-readable indicia (such as barcode **919**) or textual indicia that indicates, for instance, a test number, code number, lot number, or other desired information.

[**0045**] With reference to **FIG. 11**, the illustrated kit **1100** includes the specimen collection device **900** illustrated in **FIG. 9**, and numerous other components, some or none or all of which in practice may be included in a kit. The kit includes a barrier pouch **1103**, a dessicant pouch **1104**, a lancet **1102**, and instruction sheet separate from the kit, a results form from a previous test, and a requisition form as specifically shown in the figure. In preferred embodiments, the kit includes a mailing device, most preferably a pread-dressed envelope with postage prepaid for sending the collection device to a testing facility or other appropriate facility. In practice, the kit may further include a bandage, gauze pad, and alcohol pad for use with drawing blood from the patient (not shown) and a form for providing informal consent, which informed consent may be provided anonymously as described in the heretofore mentioned Quattrocchi patents. The barrier pouch should be a pouch that is effective in protecting the dried blood sample during shipping. One suitable barrier material is sold by Caltex Plastics of Vernon, Calif. and comprises a multi-layer barrier film consisting of 25 bleach MG Paper, 48 GA polyester film, 0.0005 aluminum foil, and 0.003 EVA co-polymer, the layers being adhesively bonded together. The pouch preferably is formed with at least one self-sealing device, such as a "zipper" disposed at at least one end of the pouch. A pouch that includes two self-scaling devices, one at each end of the pouch, alternatively may be provided.

[**0046**] The dessicant pouch should be a porous container that includes suitable dessicant effective to provide a dessicating protective effect on a blood fluid specimen, and to some extent to protect the integrity of the collection device during transport to the physician or patient. Any suitable dessicant material may be used in conjunction with the invention. One suitable dessicant is made by SudChemie of Balen, N. Mex. under part number 4286. This material comprises silica and clay disposed in admixture in a 5 gram pouch. Any other suitable dessicant may be used in conjunction with the invention.

[0047] Likewise, any suitable lancet may be employed in conjunction with the invention. The illustrated lancet **1102** preferably comprises a blood-obtaining lancet such as that presently available from Palco Labs of Santa Cruz, Calif. as the EZ-LETS II. This device includes a single-use lancet that is spring-loaded to enable the lancet to sharply pierce a user's skin. Any other suitable lancet may be used in conjunction with the invention. The barrier film pouch is sized to receive the fluid collection device. Preferably, the pouch is sized to receive the dessicant pouch and the fluid collection device.

[0048] An instruction set may be included as a separate sheet within the kit, or alternatively the instructions may be integral with (for example, imprinted on) the fluid collection device. The kit may further include results from a previous test. Such is useful, for example, in the case of patients who require periodic testing, for instance, of blood cholesterol. The invention encompasses in some embodiments a method of providing a test kit and test results to a health care provider and/or a patient, the test results being results from a previous test and the test kit being a kit as heretofore described. In some embodiments, the patient responds to an indication in the results form as to whether or when to obtain a subsequent blood sample or other type of sample.

[0049] The invention contemplates methods wherein a physician is provided with a test kit as heretofore described and wherein the patient's blood is drawn at the direction of the physician or other health care provider, either at the premises of the health care provider or elsewhere without the healthcare provider being present. In keeping with these embodiments, the kit may include a requisition form, the requisition form permitting indication of the type of test or tests to be conducted on the fluid to be collected by the device. In some embodiments, the requisition form lists a plurality of test types, and the healthcare provider need only indicate (such as with a check mark) the type of test desired. On any such form, space may be indicated for the health care provider to indicate any other sort of test desired to be conducted.

[0050] In a highly preferred embodiment of the invention, the fluid collector is an absorbent paper or glass fiber substrate that is coated with a saccharide, preferably a mono or di-saccharide and most preferably xylose. The saccharide should be present in contact with the substrate in an amount effective to inhibit triglycerides ordinarily present in the expected blood sample from binding to the fiber matrix. The substrate should be one that permits at least substantial separation of the red blood cell component of blood cells from other portions of the blood (i.e., serum). It is believed that the saccharide component permits more effective recovery of the serum components from the substrate sheet. The substrate may be coated only at the surface on one or both sides with the saccharide, but preferably the substrate is coated on internal surfaces as well as on the exterior surface. In one embodiment, 180 μl of a 5% solution of xylose is applied to the internal surface of the 0.8×7 cm substrate (such that substantially all of the substrate is wetted) and allowed to air dry. If the fluid collector is used in the device shown in **FIGS. 9 and 10**, the blood cells will remain near the end of the collection device (opposite the direction of arrow **913**) while the serum will wick toward the other end of the card. Upon receipt by a testing laboratory, a portion of the fluid collector may be excised and eluted. Preferably, the excised portion includes a portion of the collector "above" the terminal wicking point of the serum. One commercial product (Whatman GF/AVA paper) contains sodium, and it is believed that by excising filter paper above the terminal wicking point a consistent amount of sodium will be introduced into the eluted fluid. The device may be prepared by applying a solution of the saccharide to the substrate.

[0051] The glass fiber paper heretofore described comprises a mat of glass fibers that are at least substantially coated with polyvinyl alcohol. The fibers define a plurality of pores that have a pore size that, in preferred embodiments of the invention, is effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking. Any suitable substrate that provides such a pore size and that permits such substantial separation in the absence of blood cell lysing may be used in conjunction with the invention. Preferably, the average pore size defines a fluid removal rating, as this term is used in conjunction with filtration technology, of 1.7 micron.

[0052] The invention enables venous blood analyte levels to be determined from capillary blood specimens. It is contemplated that in most embodiments the solution analyte level will be normalized to the venous blood level of the analyte, but it is also contemplated that the solution value may be normalized to capillary blood level (or for that matter a different blood level).

[0053] The databases discussed herein may be created and stored as computer files on a computer readable medium, such as a diskette, hard disk, CD-ROM, DVD-ROM, ROM chip or EPROM chip, or any other suitable medium as may be now known or hereinafter discovered. The tests for the analyte and normalizing analytes may be performed by any conventional or otherwise suitable technique now or hereinafter found to be suitable, and likewise the analyte and normalizing analyte (which may be discrete atoms, ions, compounds, biochemical materials, or properties) may be those specifically described herein or others as may be found suitable for use in conjunction with the invention.

[0054] The following examples are provided to illustrate the invention, but should not be construed as limiting the invention in scope unless otherwise indicated. Unless otherwise indicated in these examples, the measured analyte level was corrected using sodium as the sole normalizing analyte. The correction was made using a simple linear regression. It should be understood that more complex single variable and multivariate regressions may be used in conjunction with the invention, and thus the statistical techniques employed in these examples should be viewed as non-limiting. EXAMPLE 1

[0055] This example demonstrates the performance of the invention in the measurement of total cholesterol.

[0056] Fifteen patients were used to obtain blood specimens (micro-serum specimens) via venal puncture. Serum from each specimen was spotted and dried on filter paper with applied volumes ranging from approximately 8 to 16 μl. The number of spots for each blood specimen is listed in the column "No." in the table below. Each spot was eluted and measured for cholesterol and sodium. For each specimen for each patient, the normalized cholesterol level was calculated

based on the level of a measured analyte in the fluid (cholesterol) and a normalizing analyte (sodium). The normalized cholesterol level was obtained according to the present invention using linear regression techniques to yield the following function: Normalized Cholesterol=Measured Cholesterol/((−0.003306)+0.9781×(Measured Sodium/13)), where 139 (mEq/L) is the population mean for sodium. The regression was calculated based on five direct measurements of the cholesterol level from the same blood sample, as listed in the column "Mean Serum Cholesterol." The mean average of the normalized cholesterol values for each patient is given in the column "mean normalized cholesterol" and the coefficient of variation of the normalized cholesterol levels obtained for each patient is listed in the column designated "Normalized Cholesterol CV %."

Patient	No.	Mean Serum Cholesterol	Mean Normalized Cholesterol	Normalize Cholesterol CV %
A	11	152.35	153.68	3.85
Ja	12	165.79	162.50	1.42
Il	14	180.93	180.47	4.61
Ca	12	186.20	182.28	0.70
Br	10	187.06	185.35	2.93
Mi	12	187.14	186.21	1.85
Gr	12	187.42	189.14	1.65
Ed	12	200.38	197.18	1.36
Tr	11	220.83	221.89	2.00
Bb	11	232.65	233.06	1.89
Ma	11	236.73	245.53	1.02
Jo	11	237.37	237.24	1.95
JJ	14	262.41	259.24	1.75
Kt	12	264.30	268.23	1.86
TT	13	269.36	273.53	2.79

[0057] A comparative linear regression was generated for the data points collected in this Example. The linear fit followed the following equation:

$$\text{Mean Normalized Cholesterol} = -7.97 + 1.04 \times \text{Mean Serum Cholesterol}$$

[0058] with the correlation coefficient, expressed as R^2, being greater than 0.99.

EXAMPLE 2

[0059] This example demonstrates the performance of the invention in the measurement of HDL.

[0060] The same dried spots from the same fifteen patients in Example 1 were used to obtain a measured value for HDL. The normalized HDL level was obtained according to the present invention using linear regression techniques yielding the following function:

[0061] Normalized HDL=HDL/(0.0158+1.060×(Sodium/139)). The following data was measured or calculated in the same manner as in Example 1.

Patient	No.	Mean Serum HDL	Mean Normalized HDL	Normalized HDL CV %
Il	14	45.77	47.03	2.35
A	11	46.05	47.77	2.17
Jo	11	47.40	48.50	2.12

-continued

Patient	No.	Mean Serum HDL	Mean Normalized HDL	Normalized HDL CV %
Ja	12	48.87	53.22	2.23
JJ	14	49.07	48.15	1.68
Gr	12	49.64	52.45	1.62
Mi	12	59.96	58.95	1.69
Br	10	57.20	55.83	2.66
Ed	12	71.00	71.09	0.92
Kt	12	73.08	72.46	1.53
TT	13	76.16	75.77	2.27
Ca	12	78.01	75.93	1.50
Bb	11	78.77	73.35	1.99
Ma	11	87.84	84.75	0.94
Tr	11	91.15	86.42	1.46

[0062] A comparative linear regression was generated for the data points collected in this Example. The linear fit followed the following equation:

$$\text{Mean Normalized HDL} = 8.15 + 0.87 \times \text{Mean Serum HDL}$$

[0063] with the correlation coefficient, expressed as R^2, being greater than 0.99.

EXAMPLE 3

[0064] This example demonstrates the performance of the invention in the measurement of triglycerides (TG).

[0065] The same dried spots from the same fifteen patients in Example 1 were used to obtain a measured value for TG. The normalized TG level was obtained according to the present invention using linear regression techniques yielding the following function:

[0066] Normalized TG=TG/((−0.0136)+0.9307×(Sodium/139)). The following data was measured or calculated in the same manner as in Example 1.

Patient	No.	Mean Serum TG	Mean Normalized TG	Normalized TG CV %
Ca	12	37.63	38.76	1.95
Bb	11	46.86	48.55	1.75
A	11	48.75	50.16	2.73
Ja	12	49.68	49.94	3.31
Kt	12	52.15	48.19	1.32
Br	10	55.00	56.56	4.14
Ma	11	56.05	56.40	2.03
Il	14	59.09	60.88	6.22
Ed	12	62.91	61.65	1.25
Tr	11	66.69	67.66	1.63
TT	13	68.76	72.14	13.37
Mi	12	71.84	72.63	1.62
Jo	11	109.28	107.10	2.27
JJ	14	117.31	112.24	5.03
Gr	12	139.47	136.74	2.13

[0067] A comparative linear regression was generated for the data points collected in this Example. The linear fit followed the following equation:

$$\text{Mean Normalized TG} = 3.36 + 0.95 \times \text{Mean Serum TG}$$

[0068] with the coefficient, expressed as R^2, being greater than 0.995.

EXAMPLE 4

[0069] This example demonstrates the performance of the invention in the measurement of LDL. The same observations from the same fifteen patients in Example 1, 2 and 3 were used to calculate a value for LDL in serum and a value for LDL in MSS according to the Friedewald formula:

Mean Serum LDL=Mean Serum Cholesterol−Mean Serum HDL−Mean Serum TG/5

Mean Normalized LDL=Mean Normalized Cholesterol−Mean Normalized HDL−Mean Normalized TG/5, respectively.

[0070] The following data was calculated (mean serum LDL was calculated from the mean values reported in Examples 1-3)

Patient	No.	Mean Serum LDL	Mean Normalized LDL	Normalized LDL CV %
A	11	96.55	95.30	5.36
Ca	12	100.66	98.82	1.17
Ja	12	106.98	99.22	2.32
Gr	12	109.88	109.00	2.19
Mi	12	115.81	112.90	2.80
Ty	11	116.35	121.21	3.11
Ed	12	116.80	113.76	1.98
Br	10	118.86	118.21	3.23
Ii	14	123.34	119.75	5.72
Ma	11	137.68	149.45	1.72
Bb	11	144.51	150.01	2.12
Jo	11	168.11	167.55	2.66
Tt	13	179.45	183.33	3.33
Kt	12	180.78	186.13	2.19
JJ	14	189.88	189.54	1.89

[0071] A comparative linear regression was generated for the data points collected in this Example. The linear fit followed the following equation:

Mean Normalized LDL=−8.16+1.07 ×Mean Serum LDL.

[0072] with the correlation, expressed as R^2, being equal to 0.98.

EXAMPLE 5

[0073] This example demonstrates the performance of the invention in the measurement of total cholesterol.

[0074] One hundred thirty-two patients were used to obtain blood via venal puncture (venous blood specimens) and by pricking their fingers (capillary blood specimens). Capillary blood was spotted on xylose-coated Whatman GF/AVA filter paper, using a device similar to that shown in **FIG. 9**. Capillary blood specimens were dried and the portion of the filter paper which contained separated serum was cut out and eluted. Eluate from each specimen was measured for cholesterol and sodium. The normalized cholesterol level was obtained according to the present invention using a variable formula: Normalized Cholesterol= Measured Cholesterol/(A+B×(Measured Sodium/139)). In this equation, A and B were scalar values that were periodically recalculated based on the "tare" procedure heretofore described, whereby a regression for six patients was calculated and the A and B values from this regression were used to calculate normalized cholesterol values for specimens analyzed before the next tare period. Actual (directly measured in venous blood) and calculated normalized cholesterol valves for these patients are given below.

Patient	Serum Cholesterol	Normalized Cholesterol
1	172.68	157.54
2	149.25	154.61
3	176.81	175.60
4	189.78	187.41
5	170.38	173.03
6	189.67	188.80
7	130.52	128.80
8	266.76	276.31
9	151.29	152.49
10	219.86	211.23
11	242.00	251.07
12	232.41	230.66
13	173.09	176.48
14	190.89	190.86
15	264.47	260.46
16	236.18	244.49
17	272.58	279.76
18	240.29	228.83
19	169.32	166.57
20	192.02	195.03
21	239.83	235.33
22	225.13	225.13
23	169.40	156.05
24	197.93	183.67
25	151.59	146.26
26	235.43	247.88
27	178.84	170.79
28	196.40	191.34
29	240.99	230.52
30	171.53	173.95
31	229.43	229.43
32	217.54	223.84
33	187.23	183.58
34	175.68	173.95
35	174.69	172.34
36	251.23	249.20
37	203.70	185.98
38	123.30	114.96
39	136.04	127.97
40	251.33	243.27
41	216.14	218.02
42	145.14	156.86
43	208.58	203.43
44	250.25	245.07
45	235.76	250.40
46	193.19	187.83
47	211.75	223.38
48	221.15	226.04
49	199.41	196.35
50	249.35	259.44
51	166.46	165.63
52	154.64	151.56
53	187.36	190.37
54	256.78	260.40
55	230.59	222.39
56	208.57	224.14
57	183.92	181.28
58	159.73	156.20
59	155.31	153.59
60	205.29	197.61
61	204.49	198.97
62	219.21	221.45
63	122.83	114.88
64	175.13	176.48
65	201.35	211.70
66	216.66	209.09
67	227.50	231.96
68	151.28	153.23
69	130.10	128.40
70	175.95	173.45
71	182.38	183.21

-continued

Patient	Serum Cholesterol	Normalized Cholesterol
72	201.03	195.89
73	175.86	189.73
74	146.10	149.88
75	116.17	103.88
76	193.58	197.59
77	291.91	296.11
78	184.93	185.49
79	145.82	141.34
80	182.73	180.78
81	175.84	170.03
82	148.99	151.67
83	212.79	213.40
84	228.82	225.39
85	218.44	229.26
86	169.43	173.84
87	151.43	157.96
88	217.96	218.63
89	239.39	244.11
90	148.62	152.86
91	136.81	132.60
92	115.13	113.31
93	121.10	119.61
94	165.31	163.34
95	111.65	132.34
96	190.25	184.44
91	201.78	206.49
98	133.26	137.69
99	225.84	221.61
100	244.66	230.25
101	164.72	168.10
102	150.75	146.82
103	163.51	110.41
104	196.06	198.89
105	213.32	206.01
106	186.62	183.13
107	163.46	162.71
108	244.58	250.24
109	231.82	231.32
110	171.94	172.27
111	201.12	209.36
112	205.41	209.00
113	157.54	156.02
114	191.41	190.59
115	192.20	197.31
116	193.82	183.12
117	257.83	248.49
118	178.32	171.44
119	203.64	209.32
120	210.36	230.25
121	207.14	220.04
122	200.05	205.38
123	216.34	219.09
124	190.10	179.14
125	293.34	272.48
126	228.57	226.02
127	111.60	174.88
128	142.80	148.94
129	197.16	205.05
130	220.50	218.43
131	230.32	231.50
132	255.18	255.23

[0075] A comparative linear regression was generated for the data points collected in this Example. The linear fit followed the following equation:

Normal Cholesterol=−1.16+1.00 ×Serum Cholesterol,

[0076] with the correlation coefficient, expressed as R^2, being 0.966.

EXAMPLE 6

[0077] This example demonstrates the performance of the invention in the measurement of HDL. The dried spots and venous blood specimens from the same one hundred Thirty-two patients in Example 5 were used to measure HDL in capillary blood it to a measured value for HDL in venous blood. The normalized HDL level in capillary blood was obtained according to the present invention using a formula: Normalized HDL=Measured HDL/(A+Bx(Measured Sodium/139)), where A and B were obtained as previously described. The following results were observed.

Patient	Serum HDL	Normalized HDL
1	58.90	61.12
2	41.28	42.33
3	38.54	39.15
4	48.84	46.19
5	61.56	54.98
6	52.68	48.79
7	47.69	45.15
8	34.69	39.49
9	57.45	56.32
10	38.00	36.33
11	47.53	42.14
12	60.04	58.94
13	36.08	37.35
14	46.09	48.37
15	42.22	42.82
16	34.70	38.98
17	55.76	55.79
18	21.16	24.53
19	55.33	55.69
20	44.66	42.65
21	83.26	81.00
22	44.33	46.14
23	40.71	40.69
24	47.24	43.98
25	49.46	47.71
26	44.37	43.30
27	50.16	48.34
28	55.49	61.30
29	58.90	61.12
30	41.28	42.33
31	38.54	39.15
32	48.84	46.19
33	61.56	54.98
34	52.68	48.79
35	47.69	45.15
36	34.69	39.49
37	57.45	56.32
38	38.00	36.33
39	47.53	42.14
40	60.04	58.94
41	36.08	37.35
42	46.09	48.37
43	42.22	42.82
44	34.70	38.98
45	55.76	55.79
46	21.16	24.53
47	55.33	55.69
48	44.66	42.65
49	83.26	81.00
50	44.33	46.14
51	40.71	40.69
52	47.24	43.98
53	49.46	47.71
54	44.37	43.30
55	50.16	48.34
56	55.49	61.30
57	49.27	45.94
58	51.73	51.78
59	38.07	36.98

-continued

Patient	Serum HDL	Normalized HDL
60	38.22	38.49
61	43.57	45.05
62	54.16	51.46
63	38.66	34.13
64	50.14	48.65
65	57.94	54.11
66	46.02	44.67
67	49.21	52.36
68	43.15	45.31
69	37.20	38.42
70	49.66	50.00
71	63.00	65.28
72	79.92	79.17
73	37.12	44.57
74	59.14	60.35
75	32.49	28.57
76	56.08	59.37
77	64.22	70.04
78	46.54	48.66
79	37.68	37.28
80	75.41	74.70
81	44.06	44.73
82	40.65	40.88
83	93.40	91.97
84	40.97	47.04
85	69.63	75.17
86	36.13	38.81
87	34.88	36.42
88	43.90	49.40
89	63.29	66.41
90	49.21	49.65
91	29.54	31.27
92	49.30	49.87
93	35.82	34.39
94	49.66	51.20
95	39.01	39.79
96	36.92	34.49
97	43.40	43.45
98	48.70	45.97
99	42.15	41.04
100	59.09	55.11
101	49.46	47.04
102	33.36	29.81
103	49.36	47.93
104	43.02	39.12
105	39.81	41.06
106	60.29	56.62
107	59.84	55.33
108	84.77	82.31
109	55.20	55.72
110	54.77	56.06
111	69.16	67.30
112	38.18	40.50
113	37.11	36.49
114	51.31	49.24
115	39.69	42.54
116	61.17	56.56
117	29.94	30.25
118	75.50	77.62
119	56.94	57.49
120	68.89	71.30
121	37.89	40.82
122	73.57	72.14
123	78.31	78.16
124	48.88	47.45
125	83.96	79.26
126	95.12	92.48
127	51.44	52.50
128	38.88	38.10
129	41.70	44.58
130	47.80	46.74
131	56.42	59.35
132	55.14	56.98

[0078] A comparative linear regression was generated for the data points collected in this Example. The linear fit followed the following equation:

$$\text{Normalized HDL}=2.47+0.953\times\text{Serum HDL}$$

[0079] with the correlation coefficient, expressed as R^2, being greater than 0.96.

EXAMPLE 7

[0080] this example demonstrates the performance of the invention in the measurement of triglycerides (TG). The dried spots and venous blood specimens from the same one hundred thirty-two patients in Example 5 were used to measure TG in capillary blood compare it to a measured value for TG in venous blood. The normalize (TG) level in capillary blood was obtained according to the present invention using the formula: Normalized TG=Measured TG/(A+B×(Measured Sodium/139)), where A and B were obtained as previously described. The following results were observed.

Patient	Serum TG	Normalized TG
1	73.24	55.65
2	97.89	97.31
3	45.26	38.38
4	70.31	60.30
5	119.71	119.33
6	105.97	100.56
7	77.47	73.30
8	220.18	236.94
9	191.79	203.18
10	177.10	177.03
11	112.19	116.71
12	73.24	55.65
13	97.89	97.31
14	45.26	38.38
15	70.31	60.30
16	119.71	119.33
17	157.70	164.69
18	122.09	124.56
19	66.86	63.24
20	138.31	151.08
21	146.08	137.36
22	95.85	97.05
23	77.27	60.69
24	85.44	82.87
25	86.25	77.32
26	112.51	110.68
27	176.25	184.16
28	190.63	189.57
29	95.17	98.92
30	98.52	98.76
31	102.13	97.07
32	117.77	128.91
33	123.08	125.56
34	135.72	132.69
35	76.46	71.14
36	230.90	210.77
37	80.41	67.66
38	99.43	85.63
39	86.87	91.07
40	125.01	120.98
41	362.90	322.04
42	132.98	118.47
43	83.21	75.43
44	52.45	53.34
45	53.91	50.52
46	349.76	357.87
47	135.25	139.57
48	209.20	208.33

-continued

Patient	Serum TG	Normalized TG
49	374.36	386.86
50	74.90	79.81
51	395.31	369.34
52	56.38	54.87
53	217.08	258.78
54	52.83	71.35
55	136.53	144.81
56	115.98	118.45
57	78.41	62.45
58	70.38	65.13
59	91.00	68.59
60	180.98	179.72
61	163.32	188.88
62	72.16	65.05
63	102.89	101.45
64	50.24	49.05
65	184.45	195.42
66	183.07	194.25
67	65.28	65.04
68	111.40	109.43
69	67.25	87.27
70	74.92	72.25
71	100.19	105.33
72	136.82	132.52
73	119.29	129.90
74	119.76	119.83
75	121.90	125.90
76	75.55	80.65
77	74.44	89.06
78	226.78	243.05
79	71.19	78.23
80	98.89	93.66
81	127.93	135.56
82	333.65	352.31
83	97.18	91.96
84	139.77	133.20
85	73.23	72.05
86	160.00	148.64
87	131.69	133.49
88	69.07	66.79
89	271.22	248.43
90	91.86	98.00
91	231.14	224.76
92	153.65	171.85
93	115.95	107.16
94	263.50	257.68
95	95.38	92.85
96	143.96	125.21
97	110.10	131.36
98	97.72	93.75
99	158.22	151.23
100	123.80	127.26
101	279.56	271.61
102	192.26	176.02
103	59.41	59.23
104	197.04	186.32
105	182.29	170.98
106	96.16	91.53
107	80.46	72.56
108	65.55	68.16
109	215.37	210.92
110	186.09	191.14
111	96.41	96.52
112	78.68	80.54
113	83.96	73.13
114	207.32	208.03
115	37.41	37.32
116	103.17	93.38
117	193.21	210.21
118	119.46	103.27
119	67.57	58.99
120	119.56	117.34
121	75.42	52.90
122	311.18	315.01

-continued

Patient	Serum TG	Normalized TG
123	67.72	68.28
124	127.36	129.28
125	59.82	64.57
126	85.54	83.90
127	43.24	41.49
128	85.09	78.05
129	95.15	99.45
130	92.21	75.05
131	72.46	88.51
132	56.52	57.13

[0081] A comparative linear regression was generated for the data points collected in this Example. The linear fit followed the following equation:

$$\text{Normalized TG}=-2.5+1.01\times\text{Serum TG},$$

[0082] with the coefficient, expressed as R^2, being 0.98.

EXAMPLE 8

[0083] This example demonstrates the performance of the invention in the measurement of LDL. The same observations from the same one hundred thirty-two patients in Example 5, 6 and 7 were used to calculate a value for LDL in serum and a value for LDL in MSS according to the Friedewald formula:

Serum LDL=Serum Cholesterol−Serum HDL−Serum TG/5

Normalized LDL=Normalized Cholesterol−Normalized HDL−Normalized TG/5.

[0084] The following results calculated:

Patient	Serum LDL	Normalized LDL
1	110.85	101.31
2	97.93	101.60
3	109.82	103.89
4	110.51	112.89
5	108.21	107.74
6	126.07	121.49
7	49.76	54.13
8	173.19	173.53
9	78.72	77.71
10	129.52	139.61
11	174.74	180.58
12	149.04	140.09
13	98.72	101.13
14	115.22	115.25
15	187.28	180.56
16	146.29	158.21
17	195.20	200.00
18	167.30	161.22
19	101.87	99.92
20	122.26	127.45
21	168.27	164.79
22	149.27	148.28
23	100.92	85.06
24	129.40	115.93
25	92.09	88.71
26	165.02	175.92
27	114.88	104.61
28	94.16	90.62
29	154.94	142.87
30	114.95	117.39
31	144.71	148.13

-continued

Patient	Serum LDL	Normalized LDL
32	152.62	164.12
33	105.78	111.48
34	105.62	106.95
35	101.99	102.99
36	143.96	145.31
37	119.65	105.96
38	68.65	63.55
39	78.02	75.16
40	180.50	174.23
41	110.10	109.10
42	72.00	80.58
43	124.52	118.94
44	140.68	128.72
45	165.02	178.66
46	92.96	83.43
47	145.15	156.72
48	133.07	131.63
49	105.59	101.08
50	177.71	184.34
51	102.56	101.25
52	91.72	95.09
53	123.82	129.64
54	194.21	203.38
55	144.23	138.11
56	120.42	125.06
57	120.22	122.32
58	87.42	84.13
59	107.19	106.80
60	130.18	120.03
61	124.30	115.07
62	151.99	156.98
63	61.89	58.86
64	111.54	110.38
65	128.43	143.14
66	150.60	143.35
67	150.93	153.10
68	84.28	81.94
69	68.95	66.01
70	101.92	98.27
71	104.27	101.79
72	106.22	98.91
73	93.38	96.56
74	72.72	73.88
75	63.90	56.58
76	111.92	111.11
77	160.96	155.60
78	118.95	118.43
79	80.19	77.42
80	92.68	91.67
81	99.78	95.56
82	82.00	84.09
83	105.58	108.07
84	133.61	128.66
85	130.44	134.49
86	87.08	90.07
87	85.82	87.16
88	150.87	147.80
89	123.40	126.22
90	80.33	84.64
91	78.47	76.28
92	107.81	97.16
93	65.74	66.47
94	84.06	81.90
95	53.88	67.10
96	97.42	95.63
97	119.93	127.83
98	72.69	79.87
99	144.28	143.36
100	149.12	140.94
101	96.03	102.76
102	101.29	102.50
103	101.09	108.85
104	109.96	117.58
105	136.29	126.72

-continued

Patient	Serum LDL	Normalized LDL
106	107.05	107.20
107	87.89	91.28
108	143.01	153.30
109	135.15	134.00
110	109.68	108.74
111	117.33	123.38
112	128.59	126.45
113	96.53	98.88
114	126.58	129.56
115	128.60	131.36
116	117.26	116.58
117	165.65	155.24
118	89.27	80.15
119	121.23	125.97
120	129.51	146.03
121	152.74	162.44
122	117.83	124.94
123	121.01	125.32
124	122.19	111.80
125	190.94	178.21
126	118.95	115.83
127	108.85	110.95
128	76.17	84.41
129	116.38	120.15
130	116.39	113.82
131	134.85	142.75
132	173.09	172.40

[0085] A comparative linear regression was generated for the data points collected in this Example. The linear fit followed the following equation:

$$\text{Normalized LDL} = -0.25 + 1.00 \times \text{Serum LDL},$$

[0086] with the correlation, expressed as R^2, being equal to 0.96.

[0087] It is thus seen that the invention provides a method for determining the level of an analyte in a specimen.

[0088] While particular embodiments to the invention have been described herein, the invention is not limited thereto, but to the contrary should be deemed defined by the full scope of the appended claims. All references and prior and co-pending applications cited herein are hereby incorporated by reference in their entireties.

What is claimed is:

1. A fluid collector comprising an absorbent substrate coated with a saccharide, said substrate comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking.

2. A fluid collector according to claim 1, the average pore size defining a fluid removal rating of 1.7 micron.

3. A fluid collector according to claim 1, said saccharide comprising xylose.

4. A fluid collection device comprising the fluid collector of claim 1 and a superstrate, said fluid collector being generally fixed with respect to said superstrate, said superstrate having an aperture defining a blood receiving opening and permitting access to said fluid collector.

5. A fluid collection device according to claim 4, said fluid collector having a first end and a second end, said aperture

permitting fluidic access to said first end of said collector, said superstrate having a second aperture relatively proximal said second end of said fluid collector.

6. A fluid collection device comprising a pair of fluid collectors, each in accordance with claim 1 and a single superstrate, said fluid collectors ordinarily not being in fluidic contact with one another and each being generally fixed with respect to said superstrate, said superstrate having a pair of apertures, each defining a blood receiving opening and permitting access to a respective one of said fluid collectors.

7. A fluid collection device according to claim 6, said superstrate comprising a second pair of apertures, each of said fluid collectors having a first end and a second end, said blood receiving openings permitting respectively fluidic access to the first end of one of said fluid collectors, said second pair of apertures each being respectively relatively proximal said second end of one of said fluid collectors thereby defining a pair of gangs.

8. A kit comprising the fluid collection device of claim 4 and instructions for using the collection device.

9. A kit according to claim 8, said instructions being integral with said device.

10. A kit according to claim 8, said instructions being separate from said device.

11. A kit comprising the fluid collection device of claim 4 and a requisition form, said requisition form permitting indication of the type of test to be conducted on the fluid to be collected by the device.

12. A test according to claim 11, said requisition form listing a plurality of test types.

13. A kit comprising the fluid collection device of claim 4 and a dessicant, said dessicant being present in an amount effective to provide a dessicating protective effect on a blood fluid specimen.

14. A kit according to claim 13, said dessicant comprising silica.

15. A kit according to claim 14, said dessicant being contained in a porous pouch.

16. A kit comprising the fluid collection device of claim 4 and a lancet.

17. A kit comprising the fluid collection device of claim 4 and a barrier film pouch sized to receive said fluid collection device.

18. A kit according to claim 17, said barrier film pouch comprising a laminar structure that includes a polyester film and an aluminum foil film.

19. A kit according to claim 17, said pouch comprising at least one self-sealing device.

20. A kit comprising:

the fluid collection device of claim 4;

a lancet;

instructions for using the kit;

a dessicant, said dessicant being present in an amount effective to provide a dessicating protective effect on a blood fluid specimen collected in said device; and

a barrier film pouch sized for receiving said fluid collection device and said dessicant.

21. A kit according to claim 20, further comprising a requisition form permitting indication of the type of test to be conducted in the fluid to be collected by the device.

22. A method for collecting a specimen from a patient, comprising:

providing a fluid collector, said fluid collector comprising an absorbent substrate coated with a saccharide, said substrate comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking; and allowing said patient to bleed onto said for collector until at least a predetermined adequate amount of blood has been deposited onto said collector.

23. A method according to claim 22, said fluid collector being included in a fluid collection device that includes a sample adequacy indicator.

24. A method according to claim 23, said sample adequacy indicator including an aperture that is spaced from the point of introduction of fluid onto said collector.

25. A method according to claim 22, further comprising sending the collector to a remote location for testing.

26. A method according to claim 25, comprising sealing the collector in a barrier film pouch.

27. A method according to claim 26, said barrier film pouch comprising a laminar structure that includes a polyester film and an aluminum foil film.

28. A method according to claim 26, further comprising adding a dessicant to said barrier film pouch, said dessicant being present in an amount effective to provide a dessicating protective effect on a blood fluid specimen.

29. A method according to claim 28, said dessicant comprising silica.

30. A method according to claim 25, further comprising receiving a results reporting form after sending said collector to a remote location for testing.

31. A method according to claim 22, further comprising indicating a type of test desired on a requisition form.

32. A method for collecting a specimen, comprising receiving a fluid collector, said fluid collector comprising a mat of glass fibers at least substantially coated with polyvinyl alcohol, said fibers defining a plurality of pores, the pores in said mat having a pore size effective to at least substantially prevent lysing of red blood cells while permitting at least substantial separation of serum from red blood cells via differential wicking; and bleeding onto said collection until at least a predetermined adequate amount of blood has been deposited onto said collector.

33. A method according to claim 32, said fluid collector being included in a fluid collection device that includes a sample adequacy indicator.

34. A method according to claim 33, said sample adequacy indicator including a aperture that is spaced from the point of introduction of fluid onto said collector.

35. A method according to claim 32, further comprising sending the collector to a remote location for testing.

36. A method according to claim 35, comprising sealing the collector in a barrier film pouch.

37. A method according to claim 36, said barrier film pouch comprising a laminar structure that includes a polyester film and an aluminum foil film.

38. A method according to claim 36, further comprising adding a dessicant to said barrier film pouch, said dessicant

said dessicant being present in an amount effective to provide a dessicating protective effect on a blood fluid specimen.

39. A method according to claim 38, said dessicant comprising silica.

40. A method according to claim 35, further comprising receiving a results reporting form after sending said collector to a remote location for testing.

41. A method for providing a test and test results to a patent, comprising providing a kit, said kit comprising:

the fluid collection device of claim 4;

a lancet;

a dessicant, said dessicant being present in an amount effective to provide a dessicating protective effect on a blood fluid specimen collected in said device; and

a barrier film pouch sized for receiving said fluid collection device and said dessicant; and

results from a previous test of the patient.

* * * * *

Merriam-Webster's Collegiate® Dictionary

TENTH EDITION

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anx·i·ety \aŋ-ˈzī-ə-tē\ *n, pl* **-eties** [L *anxietas,* fr. *anxius*] (ca. 1525) **1 a** : painful or apprehensive uneasiness of mind usu. over an impending or anticipated ill **b** : fearful concern or interest **c** : a cause of anxiety **2** : an abnormal and overwhelming sense of apprehension and fear often marked by physiological signs (as sweating, tension, and increased pulse), by doubt concerning the reality and nature of the threat, and by self-doubt about one's capacity to cope with it *syn* see CARE

an·xi·o·lyt·ic \ˌaŋ-zē-ō-ˈli-tik, ˌaŋ(k)-sē-\ *n* [*anxiety* + *-o-* + *-lytic*] (1965) : a drug that relieves anxiety — **anxiolytic** *adj*

anx·ious \ˈaŋ(k)-shəs\ *adj* [L *anxius;* akin to L *angere* to strangle, distress — more at ANGER] (ca. 1616) **1** : characterized by extreme uneasiness of mind or brooding fear about some contingency : WORRIED **2** : characterized by, resulting from, or causing anxiety : WORRYING **3** : ardently or earnestly wishing *syn* see EAGER — **anx·ious·ly** *adv* — **anx·ious·ness** *n*

[1]**any** \ˈe-nē\ *adj* [ME, fr. OE *ǣnig;* akin to OHG *einag* any, OE *ān* one — more at ONE] (bef. 12c) **1** : one or some indiscriminately of whatever kind: **a** : one or another taken at random ⟨ask ~ man you meet⟩ **b** : EVERY — used to indicate one selected without restriction ⟨~ child would know that⟩ **2** : one, some, or all indiscriminately of whatever quantity: **a** : one or more — used to indicate an undetermined number or amount ⟨have you ~ money⟩ **b** : ALL — used to indicate a maximum or whole ⟨needs ~ help he can get⟩ **c** : a or some without reference to quantity or extent ⟨grateful for ~ favor at all⟩ **3 a** : unmeasured or unlimited in amount, number, or extent ⟨~ quantity you desire⟩ **b** : appreciably large or extended ⟨could not endure it ~ length of time⟩

[2]**any** *pron, sing or pl in constr* (bef. 12c) **1** : any person or persons : ANYONE **2 a** : any thing or things **b** : any part, quantity, or number

[3]**any** *adv* (14c) : to any extent or degree : AT ALL ⟨was never ~ good⟩

any·body \-ˌbä-dē, -bə-\ *pron* (14c) : any person : ANYONE

any·how \-ˌhau̇\ *adv* (1690) **1 a** : in any manner whatever **b** : in a haphazard manner **2 a** : at any rate **b** : in any event

any·more \ˌe-nē-ˈmōr, -ˈmȯr\ *adv* (14c) **1** : any longer ⟨I was not moving ~ with my feet —Anaïs Nin⟩ **2** : at the present time : NOW ⟨hardly a day passes without rain ~⟩

usage Although both *anymore* and *any more* are found in written use, in the 20th century *anymore* is the more common styling. *Anymore* is regularly used in negative ⟨no one can be natural *anymore* —May Sarton⟩, interrogative ⟨do you read much *anymore*?⟩, and conditional ⟨if you do that *anymore,* I'll leave⟩ contexts and in certain positive constructions ⟨the Washingtonian is too sophisticated to believe *anymore* in solutions —Russell Baker⟩. In many regions of the U.S. the use of *anymore* in sense 2 is quite common in positive constructions, esp. in speech ⟨everybody's cool *anymore* —Bill White⟩ ⟨every time we leave the house *anymore,* I play a game called "Stump the Housebreaker" —Erma Bombeck⟩. The positive use appears to have been of Midland origin, but it is now reported to be widespread in all speech areas of the U.S. except New England.

any·one \ˈe-nē-(ˌ)wən\ *pron* (1536) : any person at all

any·place \-ˌplās\ *adv* (1916) : in any place : ANYWHERE

[1]**any·thing** \-ˌthiŋ\ *pron* (bef. 12c) : any thing whatever : any such thing

[2]**anything** *adv* (bef. 12c) : AT ALL

any·time \ˈe-nē-ˌtīm\ *adv* (1926) : at any time whatever

any·way \-ˌwā\ *adv* (13c) **1** : ANYWISE **2** : in any case : ANYHOW

any·ways \-ˌwāz\ *adv* (13c) **1 a** *archaic* : ANYWISE **b** *dial* : to any degree at all **2** *chiefly dial* : ANYHOW, ANYWAY

[1]**any·where** \-ˌ(h)wer, -ˌ(h)war, -(h)wər\ *adv* (14c) **1** : at, in, or to any place or point **2** : to any extent : AT ALL **3** — used as a function word to indicate limits of variation ⟨~ from 40 to 60 students⟩

[2]**anywhere** *n* (1924) : any place

any·wheres \-ˌ(h)werz, -ˌ(h)warz, -(h)wərz\ *adv* (1775) *chiefly dial* : ANYWHERE

any·wise \ˈe-nē-ˌwīz\ *adv* (13c) : in any way whatever : AT ALL

An·zac \ˈan-ˌzak\ *n* [*A*ustralian and *N*ew *Z*ealand *A*rmy *C*orps] (1915) : a soldier from Australia or New Zealand

A–OK \ˌā-(ˌ)ō-ˈkā\ *adv or adj* (1959) : very definitely OK

A1 \ˈā-ˈwən\ *adj* (1837) **1** : having the highest possible classification — used of a ship **2** : of the finest quality : FIRST-RATE

ao·rist \ˈā-ə-rəst, ˈe-ə-\ *n* [LL & Gk; LL *aoristos,* fr. Gk, fr. *aoristos* undefined, fr. *a-* + *horistos* definable, fr. *horizein* to define — more at HORIZON] (1581) : an inflectional form of a verb typically denoting simple occurrence of an action without reference to its completeness, duration, or repetition — **aorist** *or* **ao·ris·tic** \ˌā-ə-ˈris-tik, ˌe-ə-\ *adj* — **ao·ris·ti·cal·ly** \-ti-k(ə-)lē\ *adv*

aor·ta \ā-ˈȯr-tə\ *n, pl* **-tas** *or* **-tae** \-tē\ [NL, fr. Gk *aortē,* fr. *aeirein* to lift] (1543) : the great arterial trunk that carries blood from the heart to be distributed by branch arteries through the body — see HEART illustration — **aor·tic** \-ˈȯr-tik\ *adj*

aortic arch *n* (1903) : one of the arterial branches in vertebrate embryos that exist in a series of pairs with one on each side of the embryo, connect the ventral arterial system lying anterior to the heart to the dorsal arterial system above the alimentary tract, and persist in adult fishes but are reduced or much modified in the adult of higher forms

aor·tog·ra·phy \ˌā-ˌȯr-ˈtä-grə-fē\ *n* (ca. 1935) : arteriography of the aorta — **aor·to·graph·ic** \(ˌ)ā-ˌȯr-tə-ˈgra-fik\ *adj*

aou·dad \ˈau̇-ˌdad, ˈä-ü-\ *n* [F, fr. Berber *audad*] (1861) : a wild bovine (*Ammotrogus lervia*) of No. Africa that is closely related to goats and sheep and has been introduced into the southwestern U.S.

à ou·trance \ˌä-ˌü-ˈträⁿs\ *adv* [F] (1883) : to the limit : UNSPARINGLY

[1]**ap-** — see AD-

[2]**ap-** — see APO-

apace \ə-ˈpās\ *adv* [ME, prob. fr. MF *à pas* on step] (14c) **1** : at a quick pace : SWIFTLY **2** : ABREAST — used with *of* or *with*

Apache \ə-ˈpa-chē, *in sense 3* ə-ˈpash\ *n, pl* **Apache** *or* **Apach·es** \-ˈpa-chēz; -ˈpash, -ˈpa-shəz\ [AmerSp, perh. fr. Zuni *ʔa·paču* Navajo, Apachean] (1745) **1** : a member of a group of American Indian peoples of the southwestern U.S. **2** : any of the Athabascan languages of the Apache people **3** *not cap* [F, fr. *Apache* Apache Indian] **a** : a member of a gang of criminals esp. in Paris **b** : RUFFIAN — **Apach·e·an** \ə-ˈpa-chē-ən\ *adj or n*

ap·a·nage *var of* APPANAGE

ap·a·re·jo \ˌa-pə-ˈrā-(ˌ)(h)ō\ *n, pl* **-jos** [AmerSp] (1844) : a packsaddle of stuffed leather or canvas

[1]**apart** \ə-ˈpärt\ *adv* [ME, fr. MF *a part,* lit., to the side] (14c) **1 a** : at a little distance ⟨tried to keep ~ from the family squabbles⟩ **b** : away from one another in space or time ⟨towns 20 miles ~⟩ **2 a** : as a separate unit : INDEPENDENTLY ⟨viewed ~, his arguments were unsound⟩ **b** : so as to separate one from another ⟨found it hard to tell the twins ~⟩ **3** : excluded from consideration : ASIDE ⟨a few blemishes ~, the novel is excellent⟩ **4** : in or into two or more parts : to pieces ⟨coming ~ at the seams⟩

[2]**apart** *adj* (1786) **1** : SEPARATE, ISOLATED **2** : holding different opinions : DIVIDED — **apart·ness** *n*

apart from *prep* (1833) : other than : BESIDES

apart·heid \ə-ˈpär-ˌtāt, -ˌtīt\ *n* [Afrik, fr. D, fr. *apart* apart + *-heid* -hood] (1947) **1** : racial segregation; *specif* : a policy of segregation and political and economic discrimination against non-European groups in the Republic of So. Africa **2** : SEPARATION, SEGREGATION ⟨I favor ~ of smokers —L. E. Bellin⟩ ⟨sexual ~⟩

apart·ment \ə-ˈpärt-mənt\ *n* [F *appartement,* fr. It *appartamento*] (1641) **1** : a room or set of rooms fitted esp. with housekeeping facilities and usu. leased as a dwelling **2** : a building containing several individual apartments — **apart·men·tal** \ə-ˌpärt-ˈmen-tᵊl\ *adj*

apartment hotel *n* (1909) : a hotel containing apartments as well as accommodations for transients

apartment house *n* (1874) : a building containing separate residential apartments — called also *apartment building*

ap·a·thet·ic \ˌa-pə-ˈthe-tik\ *adj* (1744) **1** : having or showing little or no feeling or emotion : SPIRITLESS **2** : having little or no interest or concern : INDIFFERENT *syn* see IMPASSIVE — **ap·a·thet·i·cal·ly** \-ti-k(ə-)lē\ *adv*

ap·a·thy \ˈa-pə-thē\ *n* [Gk *apatheia,* fr. *apathēs* without feeling, fr. *a-* + *pathos* emotion — more at PATHOS] (1603) **1** : lack of feeling or emotion : IMPASSIVENESS **2** : lack of interest or concern : INDIFFERENCE

ap·a·tite \ˈa-pə-ˌtīt\ *n* [G *Apatit,* fr. Gk *apatē* deceit] (1803) : any of a group of calcium phosphate minerals occurring variously as hexagonal crystals, as granular masses, or in fine-grained masses as the chief constituent of phosphate rock and of bones and teeth; *esp* : calcium phosphate fluoride

apato·sau·rus \ə-ˌpa-tə-ˈsȯr-əs\ *n* [NL, fr. Gk *apatē* + *sauros* lizard] (ca. 1899) : BRONTOSAURUS

[1]**ape** \ˈāp\ *n* [ME, fr. OE *apa;* akin to OHG *affo* ape] (bef. 12c) **1 a** : MONKEY; *esp* : one of the larger tailless or short-tailed Old World forms **b** : any of two families (Pongidae and Hylobatidae) of large tailless semierect primates (as the chimpanzee, gorilla, orangutan, or gibbon) — called also *anthropoid, anthropoid ape* **2 a** : MIMIC **b** : a large uncouth person — **ape·like** \ˈāp-ˌlīk\ *adj*

[2]**ape** *vt* **aped; ap·ing** (1632) : to copy closely but often clumsily and ineptly *syn* see COPY — **ap·er** *n*

[3]**ape** *adj* (ca. 1955) : being beyond restraint : CRAZY, WILD — usu. used in the phrase *go ape*

apeak \ə-ˈpēk\ *adj or adv* [alter. of earlier *apike,* prob. fr. F *à pic* vertically] (1596) : being in a vertical position ⟨with oars ~⟩

ape–man \ˈāp-ˌman, -ˈman\ *n* (1879) : a primate (as an australopithecine) intermediate in character between Homo sapiens and the higher apes

aper·çu \ä-per-sü̅, ˌa-pər-ˈsü\ *n, pl* **aperçus** \-sü̅(z), -ˈsüz\ [F, fr. *aperçu,* pp. of *apercevoir* to perceive, fr. OF *aperceivre,* fr. *a-* (fr. L *ad-*) + *perceivre* to perceive — more at PERCEIVE] (1828) **1** : a brief survey or sketch : OUTLINE **2** : an immediate impression; *esp* : INSIGHT 2

ape·ri·ent \ə-ˈpir-ē-ənt\ *adj* [L *aperient-, aperiens,* prp. of *aperire*] (1626) : gently moving the bowels : LAXATIVE — **aperient** *n*

ape·ri·od·ic \ˌā-ˌpir-ē-ˈä-dik\ *adj* (1879) **1** : of irregular occurrence ⟨~ floods⟩ **2** : not having periodic vibrations : not oscillatory — **ape·ri·od·i·cal·ly** \-di-k(ə-)lē\ *adv* — **ape·ri·o·dic·i·ty** \-ē-ə-ˈdi-sə-tē\ *n*

aper·i·tif \ə-ˌper-ə-ˈtēf, a-; ˌä-pər-(ə-)ˈtēf\ *n* [F *apéritif* aperient, aperitif, fr. MF *aperitif,* adj., aperient, fr. ML *aperitivus,* irreg. fr. L *aperire*] (1894) : an alcoholic drink taken before a meal as an appetizer

ap·er·ture \ˈap-ə(r)-ˌchür, -chər, -ˌtyür, -ˌtür\ *n* [ME, fr. L *apertura,* fr. *apertus,* pp. of *aperire* to open] (15c) **1** : an opening or open space : HOLE **2 a** : the opening in a photographic lens that admits the light **b** : the diameter of the stop in an optical system that determines the diameter of the bundle of rays traversing the instrument **c** : the diameter of the objective lens or mirror of a telescope

apet·al·ous \(ˌ)ā-ˈpe-tᵊl-əs\ *adj* (ca. 1706) : having no petals

apex \ˈā-ˌpeks\ *n, pl* **apex·es** *or* **api·ces** \ˈā-pə-ˌsēz, ˈa-\ [L] (1601) **1 a** : the uppermost point : VERTEX ⟨the ~ of a mountain⟩ **b** : the narrowed or pointed end : TIP ⟨the ~ of the tongue⟩ **2** : the highest or culminating point ⟨the ~ of his career⟩ *syn* see SUMMIT

Ap·gar score \ˈap-ˌgär-\ *n* [Virginia *Apgar* †1974 Am. anesthesiologist] (1962) : an index used to evaluate the condition of a newborn infant based on a rating of 0, 1, or 2 for each of the five characteristics of color, heart rate, response to stimulation of the sole of the foot, muscle tone, and respiration with 10 being a perfect score

aphaer·e·sis *or* **apher·e·sis** \ə-ˈfer-ə-səs\ *n, pl* **-e·ses** \-ˌsēz\ [LL, fr. Gk *aphairesis,* lit., taking off, fr. *aphairein* to take away, fr. *apo-* + *hairein* to take] (ca. 1550) : the loss of one or more sounds or letters at the beginning of a word (as in *round* for *around* and *coon* for *raccoon*) — **aph·ae·ret·ic** \ˌa-fə-ˈre-tik\ *adj*

aph·a·nite \ˈa-fə-ˌnīt\ *n* [F, fr. Gk *aphanēs* invisible, fr. *a-* + *phainesthai* to appear — more at PHENOMENON] (ca. 1828) : a dark rock of such close texture that its separate grains are invisible to the naked eye — **aph·a·nit·ic** \ˌa-fə-ˈni-tik\ *adj*

apha·sia \ə-ˈfā-zh(ē-)ə\ *n* [NL, fr. Gk, fr. *a-* + *-phasia*] (1867) : loss or impairment of the power to use or comprehend words usu. resulting from brain damage — **apha·sic** \-zik\ *n or adj*

aph·elion \a-ˈfēl-yən\ *n, pl* **-elia** \-yə\ [NL, fr. *apo-* + Gk *hēlios* sun — more at SOLAR] (1656) : the point in the path of a celestial body (as a planet) that is farthest from the sun — compare PERIHELION

as **a** : enterable by both amateur and professional contestants ⟨an ~ tournament⟩ **b** : enterable by a registered voter regardless of political affiliation ⟨an ~ primary⟩ **6** : fit to be traveled over : presenting no obstacle to passage or view ⟨the ~ road⟩ ⟨~ country⟩ **7** : having the parts or surfaces laid out in an expanded position : spread out : UNFOLDED ⟨an ~ book⟩ **8 a** (1) : LOW 13 (2) : formed with the tongue in a lower position ⟨Italian has an ~ and a close *e*⟩ **b** (1) : having clarity and resonance unimpaired by undue tension or constriction of the throat ⟨an ~ vocal tone⟩ (2) *of a tone* : produced by an open string or on a wind instrument by the lip without the use of slides, valves, or keys **9 a** : available to follow or make use of ⟨the only course ~ to us⟩ **b** : not taken up with duties or engagements ⟨keep an hour ~ on Friday⟩ **c** : not finally decided : subject to further consideration ⟨the salary is ~⟩ ⟨an ~ question⟩ **d** : available for a qualified applicant : VACANT ⟨the job is still ~⟩ **e** : remaining available for use or filling until canceled ⟨an ~ order for more items⟩ **f** : available for future purchase ⟨these items are in ~ stock⟩ **10 a** : characterized by ready accessibility and usu. generous attitude: as (1) : generous in giving (2) : willing to hear and consider or to accept and deal with : RESPONSIVE (3) : free from reserve or pretense : FRANK **b** : accessible to the influx of new factors (as foreign goods) ⟨an ~ market⟩ **11 a** : having openings, interruptions, or spaces ⟨~ mesh⟩: as (1) : being porous and friable ⟨~ soil⟩ (2) : sparsely distributed : SCATTERED ⟨~ population⟩ (3) *of a compound* : having components separated by a space in writing or printing (as *opaque projector*) **b** : not made up of a continuous closed circuit of channels ⟨the insect circulatory system is ~⟩ **12 a** *of an organ pipe* : not stopped at the top **b** *of a string on a musical instrument* : not stopped by the finger **13** : being in operation ⟨an ~ microphone⟩; *esp* : ready for business, patronage, or use ⟨the store is ~ from 9 to 5⟩ ⟨the new highway will be ~ next week⟩ **14 a** (1) : characterized by lack of effective regulation of various commercial enterprises ⟨an ~ town⟩ (2) : not repressed by legal controls ⟨~ gambling⟩ **b** : free from checking or hampering restraints ⟨an ~ economy⟩ **c** : relatively unguarded by opponents ⟨passed to an ~ teammate⟩ **15** : having been opened by a first ante, bet, or bid ⟨the bidding is ~⟩ **16** *of punctuation* : characterized by sparing use esp. of the comma **17 a** : containing none of its endpoints ⟨an ~ interval⟩ **b** : being a set or composed of sets each point of which has a neighborhood all of whose points are contained in the set ⟨the interior of a sphere is an ~ set⟩ **18 a** : being an incomplete electrical circuit **b** : not allowing the flow of electricity ⟨an ~ switch⟩ *syn* see FRANK, LIABLE — **open** *adv* — **open·ly** \ˈō-pən-lē\ *adv* — **open·ness** \-pə(n)-nəs\ *n*

²**open** *vb* **opened** \ˈō-pənd, ˈō-pᵊmd\; **open·ing** \ˈōp-niŋ, ˈō-pə-\ *vt* (bef. 12c) **1 a** : to move (as a door) from a closed position **b** : to make available for entry or passage by turning back (as a barrier) or removing (as a cover or an obstruction) **2 a** : to make available for or active in a regular function ⟨~ a new store⟩ **b** : to make accessible for a particular purpose ⟨~*ed* new land for settlement⟩ ⟨~ the way for changes⟩ **c** : to initiate access to (a computer file) prior to use **3 a** : to disclose or expose to view : REVEAL **b** : to make more discerning or responsive : ENLIGHTEN ⟨must ~ our minds to the problems⟩ **c** : to bring into view or come in sight of by changing position **4 a** : to make an opening in ⟨~*ed* the boil⟩ **b** : to loosen and make less compact ⟨~ the soil⟩ **5** : to spread out : UNFOLD ⟨~*ed* the book⟩ **6 a** : to enter upon : BEGIN ⟨~*ed* the meeting⟩ **b** : to commence action in a card game by making (a first bid), putting a first bet in (the pot), or playing (a card or suit) as first lead **7** : to restore or recall (as an order) from a finally determined state to a state in which the parties are free to prosecute or oppose ~ *vi* **1** : to become open ⟨the office ~*ed* early⟩ **2 a** : to spread out : EXPAND ⟨the wound ~*ed* under the strain⟩ **b** : to become disclosed ⟨a beautiful vista ~*ed* before us⟩ **3** : to become enlightened or responsive **4** : to give access ⟨the rooms ~ onto a hall⟩ **5** : SPEAK OUT 2 ⟨finally he ~*ed* freely on the subject⟩ **6 a** : to begin a course or activity ⟨the play ~*s* on Tuesday⟩ **b** : to make a bet, bid, or lead in commencing a round or hand of a card game — **open·abil·i·ty** \ˌōp-nə-ˈbi-lə-tē, ˌō-pə-\ *n* — **open·able** \ˈōp-nə-bəl, ˈō-pə-\ *adj*

³**open** *n* (13c) **1** : OPENING **2** : open and unobstructed space: as **a** : OPEN AIR **b** : open water **3** : an open contest, competition, or tournament **4** : a public or unconcealed state or position

open admission *n* (1969) : OPEN ENROLLMENT 2

open–air *adj* (1830) : OUTDOOR

open air *n* (15c) : the space where air is unconfined; *esp* : OUTDOORS

open–and–shut *adj* (1841) **1** : perfectly simple : OBVIOUS **2** : easily settled ⟨an ~ case⟩

open bar *n* (1973) : a bar (as at a wedding reception) at which drinks are served free — compare CASH BAR

open·cast \ˈō-pən-ˌkast\ *adj* (ca. 1890) *chiefly Brit* : worked from a surface open to the air ⟨an ~ mine⟩ ⟨~ mining⟩

open chain *n* (1884) : an arrangement of atoms represented in a structural formula by a chain whose ends are not joined so as to form a ring

open city *n* (1914) : a city that is not occupied or defended by military forces and that is not allowed to be bombed under international law

open dating *n* (1971) : the marking of perishable food products with a clearly readable date indicating when the food was packaged or the last date on which it should be sold or used

open door *n* (1526) **1** : a recognized right of admittance : freedom of access **2** : a policy giving opportunity for commercial relations with a country to all nations on equal terms — **open–door** *adj*

open–end *adj* (1917) : organized to allow for contingencies: as **a** : permitting additional debt to be incurred under the original indenture subject to specified conditions ⟨an ~ mortgage⟩ **b** : having a fluctuating capitalization of shares that are issued or redeemed at the current net asset value or at a figure in fixed ratio to this ⟨an ~ investment company⟩ — compare CLOSED-END

open–end·ed \ˌō-pən-ˈen-dəd\ *adj* (1825) : not rigorously fixed: as **a** : adaptable to the developing needs of a situation **b** : permitting or designed to permit spontaneous and unguided responses — **open–end·ed·ness** *n*

open enrollment *n* (1964) **1** : the voluntary enrollment of a student in a public school other than the one assigned on the basis of residence **2** : enrollment on demand as a student in an institution of higher learning irrespective of formal qualifications

open·er \ˈōp-nər, ˈō-pə-\ *n* (15c) : one that opens ⟨a bottle ~⟩: as **a** *pl* : cards of sufficient value for a player to open the betting in a poker game **b** : the first item, contest, or event of a series — **for openers** : to begin with

open–eyed \ˌō-pən-ˈīd\ *adj* (1601) **1** : having the eyes open **2** : carefully observant : DISCERNING

open·hand·ed \-ˈhan-dəd\ *adj* (1593) : GENEROUS, MUNIFICENT — **open·hand·ed·ly** *adv* — **open·hand·ed·ness** *n*

open–heart *adj* (1960) : of, relating to, or performed on a heart temporarily relieved of circulatory function and surgically opened for inspection and treatment ⟨~ surgery⟩

open·heart·ed \ˌō-pən-ˈhär-təd\ *adj* (1611) **1** : candidly straightforward : FRANK **2** : responsive to emotional appeal — **open·heart·ed·ly** *adv* — **open·heart·ed·ness** *n*

open–hearth *adj* (1885) : of, relating to, involving, or produced in the open-hearth process ⟨~ steel⟩

open–hearth process *n* (1882) : a process of making steel from pig iron in a furnace of the regenerative reverberatory type

open house *n* (15c) **1** : ready and usu. informal hospitality or entertainment for all comers **2** : a house or apartment open for inspection esp. by prospective buyers or tenants

open·ing \ˈōp-niŋ, ˈō-pə-\ *n* (13c) **1 a** : an act or instance of making or becoming open **b** : an act or instance of beginning : COMMENCEMENT; *esp* : a formal and usu. public event by which something new is put officially into operation **2** : something that is open: as **a** (1) : BREACH, APERTURE (2) : an open width : SPAN **b** : an area without trees or with scattered usu. mature trees that occurs as a break in a forest **c** : two pages that face one another in a book **3** : something that constitutes a beginning: as **a** : a planned series of moves made at the beginning of a game of chess or checkers — compare ENDGAME, MIDDLE GAME **b** : a first performance **4 a** : OCCASION, CHANCE **b** : an opportunity for employment

open letter *n* (1878) : a published letter of protest or appeal usu. addressed to an individual but intended for the general public

open loop *n* (1947) : a control system for an operation or process in which there is no self-correcting action as there is in a closed loop

open marriage *n* (1971) : a marriage in which the partners agree to let each other have sexual partners outside the marriage

open–mind·ed \ˌō-pən-ˈmīn-dəd\ *adj* (1828) : receptive to arguments or ideas — **open–mind·ed·ly** *adv* — **open–mind·ed·ness** *n*

open·mouthed \ˌō-pən-ˈmau̇thd, -ˈmau̇tht\ *adj* (15c) **1** : CLAMOROUS, VOCIFEROUS **2** : having the mouth wide open **3** : struck with amazement or wonder — **open·mouth·ed·ly** \-ˈmau̇-thəd-lē, -thəd-\ *adv* — **open·mouth·ed·ness** \-ˈmau̇-thəd-nəs, -thəd-\ *n*

open–pol·li·nat·ed \ˌō-pən-ˈpä-lə-ˌnā-təd\ *adj* (1925) : pollinated by natural agencies without human intervention

open season *n* (ca. 1890) **1** : a period when it is legal to kill or catch game or fish protected at other times by law **2** : a time during which someone or something is the object of sustained attack or criticism

open secret *n* (1828) : a supposedly secret but generally known matter

open sentence *n* (1937) : a statement (as in mathematics) that contains at least one blank or unknown and that becomes true or false when the blank is filled or a quantity is substituted for the unknown

open ses·a·me \-ˈse-sə-mē\ *n* [fr. *open sesame*, the magical command used by Ali Baba to open the door of the robbers' den in *Ali Baba and the Forty Thieves*] (ca. 1837) : something that unfailingly brings about a desired end

open shop *n* (1903) : an establishment in which eligibility for employment and retention on the payroll are not determined by membership or nonmembership in a labor union though there may be an agreement by which a union is recognized as sole bargaining agent

open sight *n* (1591) : a firearm rear sight having an open notch

open stance *n* (1948) : a stance (as in golf) in which the forward foot is farther from the line of play than the back foot — compare CLOSED STANCE

open syllable *n* (1891) : a syllable ended by a vowel or diphthong

open up *vt* (1582) **1** : to make available **2** : to make plain or visible : DISCLOSE **3** : to open by cutting into ~ *vi* **1** : to spread out or come into view ⟨the road *opens up* ahead⟩ **2** : to commence firing **3** : to become communicative ⟨tried to get the patient to *open up*⟩

open·work \ˈō-pən-ˌwərk\ *n, often attrib* (1598) : work constructed so as to show openings through its substance : work that is perforated or pierced ⟨wrought-iron ~⟩ — **open–worked** \-ˌwərkt\ *adj*

¹**opera** *pl of* OPUS

²**op·era** \ˈä-p(ə-)rə, *Southern also* ˈä-prē\ *n* [It, work, opera, fr. L, work, pains; akin to L *oper-, opus* — more at OPERATE] (1644) **1** : a drama set to music and made up of vocal pieces with orchestral accompaniment and orchestral overtures and interludes; *specif* : GRAND OPERA **2** : the score of a musical drama **3** : the performance of an opera; *also* : a house where operas are performed

op·er·a·ble \ˈä-p(ə-)rə-bəl\ *adj* (1646) **1** : fit, possible, or desirable to use : PRACTICABLE **2** : likely to result in a favorable outcome upon surgical treatment ⟨an ~ cancer⟩ — **op·er·a·bil·i·ty** \ˌä-p(ə-)rə-ˈbi-lə-tē\ *n* — **op·er·a·bly** \ˈä-pə-rə-blē\ *adv*

op·éra bouffe \ˈō-pā-rä-ˈbüf, ˈä-p(ə-)rə-\ *n* [F, fr. It *opera buffa*] (1870) : satirical comic opera

opera buf·fa \-ˈbü-fə\ *n* [It, lit., comic opera] (1802) : an 18th century farcical comic opera with dialogue in recitative

opéra co·mique \-kä-ˈmēk, -kō-\ *n* [F, lit., comic opera] (1744) : an opera characterized by spoken dialogue interspersed between the arias and ensemble numbers — compare GRAND OPERA

opera glass *n* (1738) : a small low-power binocular without prisms for use at the opera or theater — often used in pl.

op·era·go·er \ˈä-p(ə-)rə-ˌgō(-ə)r\ *n* (1850) : a person who frequently goes to operas — **op·era·go·ing** \-ˌgō-iŋ, -ˌgȯ(-)iŋ\ *n*

opera hat *n* (1810) : a man's collapsible top hat

opera house *n* (1720) : a theater devoted principally to the performance of operas; *broadly* : THEATER

op·er·and \ˌä-pə-ˈrand\ *n* [L *operandum*, neut. of gerundive of *operari*] (1886) : something (as a quantity or data) that is operated on (as in a mathematical operation); *also* : the address in a computer instruction of data to be operated on

¹**op·er·ant** \ˈä-pə-rənt\ *adj* (15c) **1** : functioning or tending to produce effects : EFFECTIVE ⟨an ~ conscience⟩ **2** : of or relating to the

MECHANICS OF PATENT CLAIM DRAFTING

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John L. Landis
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popper and is to be so claimed, and that the holes in the container (Fig. 1) are important and must be defined.

Clause (a) of Claim 1 might read:

> A container for receiving kernels of corn to be popped, the container having a perforated bottom with apertures smaller in size than the kernels;

Other examples of expressions defining features of elements:

> a disc of resilient material having a peripheral groove...
> a relay having two windings...
> a lever having a forked end and a rounded end ... [If only the forked end is important to the combination being claimed, do not mention the rounded end.]
> a gear of electrically insulating material...

If an element by definition inherently includes a certain feature, such feature need not be recited and it is proper to refer, without previous mention, to such features as:

> the end of the lever...
> the periphery of the disc...
> the tines of the fork...

In case of doubt, positively describe the feature or part.

SUMMARY—Select those parts or features of each element that are essential to the combination being claimed. Then, describe them in a logical order, preferably following the main description of the element in the same clause of the claim. How many features need to be described and how broadly each should be recited is a matter of claim scope (based largely on the prior art), but the principles are the same as used in selecting the elements and naming them.

Section 23—Claiming Holes

In the situation where a hole is to be described it must not be recited positively. That is, instead of stating "a hole, groove, aper-

ture, recess, slot, etc., in the lever," one must state ". . . the lever having a hole, groove, etc." Thereafter, one can refer to "the hole" or "said hole." This "rule" may seem to make little sense, but it is another founded in antiquity like the single-sentence rule. Maybe someone thought that a hole is nothing—and people shouldn't claim nothing?

Another approach to describing holes is an expression such as ". . . the level having portions defining a hole, groove, etc." The hole is thus defined in terms of the structure which forms it.

One case *In re Newton*, 163 USPQ 34 (CCPA 1969), held that it was proper to claim a hole and its function as a means for performing a function, specifically "means for providing fluid communication between . . . [two members]."

SUMMARY—Do not claim holes positively or make them claim elements. Holes are nothing; you cannot claim nothing. Claim "a [member] having a hole," groove, slot, aperture, etc.

Section 24—Order of Elements

The elements of the claim should be presented in some logical order. Often, there are several orders that make sense, and any one may be selected. The order used in Claim 1 is a "functional" order, starting with the element which first contacts the workpiece (the container) and proceeding along functional lines to describe the remaining elements.

Another order which is often used is a "structural" order, starting first with the base, or the source of power, and proceeding along structural lines to describe the remaining elements. In structural order, Claim 1 would read:

> **1B. Apparatus for shaking articles, which comprises:**
> **(a) a base;**
> **(b) a plurality of parallel legs, each of which is connected pivotally at one end of the base;**
> **(c) a container for the articles connected pivotally to the other ends of the legs, so that the legs support the container for oscillating movement with respect to the base; and**